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No. 08-___

IN THE

# Supreme Court of the United States

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PFIZER INC.,

*Petitioner*,

v.

RABI ABDULLAHI, *et al.*,

*Respondents.*

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**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

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## PETITION FOR A WRIT OF CERTIORARI

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## QUESTIONS PRESENTED

In the midst of an unprecedented bacterial meningitis epidemic in Nigeria, petitioner Pfizer Inc. ("Pfizer") conducted a clinical trial of an antibiotic medication. Respondents filed suit in two United States district courts, invoking federal subject matter jurisdiction under the Alien Tort Statute ("ATS"), 28 U.S.C. 1350. The complaints alleged that Pfizer had violated international law by failing to obtain adequate consent from patients. They alleged that the Nigerian government assisted generally in the importation of the medicine and provision of hospital facilities, but not that the government knew of or participated in the failure to obtain adequate consent. The questions presented are:

1. Whether ATS jurisdiction can extend to a private actor based on alleged state action by a foreign government where there is no allegation that the government knew of or participated in the specific acts by the private actor claimed to have violated international law.

2. Whether, absent state action, a complaint that a private actor has conducted a clinical trial of a medication without adequately informed consent can surmount the "high bar to new private causes of action" under the ATS that this Court recognized in *Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 727 (2004).

## PARTIES AND RULE 29.6 STATEMENT

Petitioner, Pfizer Inc. ("Pfizer"), was the defendant in the consolidated district court actions and was the appellee in the Second Circuit. Pfizer has no parent company, and no publicly held company owns 10% or more of Pfizer's stock.

Respondents, individuals, were the plaintiffs in the consolidated district court actions and were the appellants in the Second Circuit. They are:

Rabi Abdullahi, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatau Abdullahi

Salisu Abullahi, individually and as the natural guardian and personal representative of the estate of his son Abulliahi (Manufi) Salisu

Alasan Abdullahi, individually and as the natural guardian and personal representative of the estate of his daughter Firdausi Abdullahi

Ali Hashimu, individually and as the natural guardian and personal representative of the estate of his daughter Suleiman

Muhammadu Inuwa, individually and as the natural guardian and personal representative of the estate of his son Abdullahi M. Inuwa

Magaji Alh Laden, individually and as the natural guardian and personal representative of the estate of his son Kabiru Isyaku

Alhaji Mustapha, individually and as the natural guardian and personal representative of the estate of his daughter Asma'u Mustapha

Suleiman Umar, individually and as the natural guardian and personal representative of the estate of his son Buhari Suleiman

Haji Abdullahi, individually and as the natural guardian of Zainab Abdu, a minor

Abdullahi Madawaki, individually and as the natural guardian of Firdausi Abdullahi, a minor

Sani Abdullahi, a minor, by his father and natural guardian, Sani Abdullahi

Aisha Ado, individually and as the natural guardian of Abdullahi Ado, a minor

Abdumajid Ali, a minor, by his father and natural guardian, Alhaji Yusuf Ali

Muhammad Ali, individually and as the natural guardian of Nura Muhammad Ali, a minor

Malam Badamasi Zubairu, individually and as the natural guardian of Umar Badamasi, a minor

Alhaji Danaldi Ibrahim, individually and as the natural guardian of Muhammadu Fatahu Danladi, a minor

Malam Gwammaja, individually and as the natural guardian of Dalha Hamza, a minor

Mukhtar Saleh, individually and as the natural guardian of Tasiu Haruna, a minor

Tijjani Hassan, individually and as the natural guardian of Muhyiddeen Haasan, a minor

Kawu Adamu Ibrahim, a minor, by his father and natural guardian, Malam Abamus Ibrahim Adamu

Alhaji Ibrahim Haruna, individually

Mallam Idris, individually

Idris Umar, individually and as the natural guardian of Yusuf Idris, a minor

Isa Muhammed Isa, individually and as the natural guardian of Hafsat Isa, a minor

Malam Isa Usman, individually and as the natural guardian of Taju Isa, a minor

Isyaku Suaibu, individually and as the natural guardian of Hadiza Isyaku, a minor

Jafaru Baba, individually and as the natural guardian of Zahra'u Jafaru, a minor

Malam Mohammed, individually and as the natural guardian of Anas Mohammed, a minor

Yahawasu Muhammed, individually and as the natural guardian of Nafisatu Muhammed, a minor

Muhsinu Tijjani, a minor, by his father and natural guardian, Tijjani Hassan

Alhaji Yusuf Ali

Maryam Idris, a minor, by her father and natural guardian, Malam Idris

Ajudu Ismaila Adamu, individually and as parent and natural guardian of Yahaya Ismaica, minor

Malam Mohammed, individually and as parent and natural guardian of Bashir Mohammed, minor

Malam Yusab Ya'u Amale, individually and as parent and natural guardian of Suyudi Yusals Yu'a, minor

Malasm Haruna Adamu, individually and as parent and natural guardian of Mohammed Tasi'u Haruna, minor

Zangon Kwajalawa, individually and as parent and natural guardian of Nuruddim Dauda, minor

Malam Dahauru Ya'y, individually and as parent and natural guardian of Rabi Dahuru, minor and as parent and natural guardian of Zainab Musa Dahuru, minor

Zangon Marikita, individually and as parent and natural guardian of Ismaila Musa, minor

Arhaji Muihammad Soja, individually and as parent and natural guardian and personal representative of estate of Hamaza Achaji Muhammad, minor, deceased

Achaji Ibrahim Dankwalba, individually and as parent and natural guardian of Personal Representative of estate of Abdullahi Ibrahim, minor

Mallam Lawan, individually and as parent and natural guardian and personal representative of estate of Aisha Lawan, minor, deceased

Alhaji Muhammed Tsohon Sojo, individually and as parent and natural guardian and personal representative of estate of Unni Alhasi Muhammed, minor

Ismaila Zubairui, individually and as parent and natural guardian and personal representative of estate of Mustapha Zubairu, minor, deceased

Abubaker Musa, individually and as parent and natural of Sa'adatu Musa, minor

Mohamed Abdu, individually and as parent and natural guardian of Haruna Abdu, minor

Mallam Hassan, individually and as parent and natural guardian and personal representative of estate of Sadiya Hassan, minor, deceased

Mallam Yakubu Umar, individually and as parent and natural guardian of Abubakar Yakubu, minor

Mallam Samaila, individually and as parent and natural guardian of Adamu Samalia, minor

Musa Yahaya, individually and as parent and natural guardian of Ukhasa Musa, minor

Audu Ismailia Adamu, individually and as parent and natural guardian of Yashaya Samaila

Malam Musa Dahiru, individually and as parent and natural guardian of Zainabu Musa, minor

Malam Musa Zango, individually and as parent and natural guardian of Samaila Musa, minor

Mallam Alhassan Maihula, individually and as a parent and natural guardian of Najib Maihula, minor

Mallam Abdullah Gama, individually and as parent and natural guardian of Dankuma Gama, minor

Dauda Nuhu, individually and as parent and natural guardian and personal representative of estate of Hamisu Nuhu, minor, deceased

Mallam Abdullahi, individually and as parent and natural guardian and personal representative of estate of Najaratu Adbullahi, minor, deceased

Malam Umaru Mohammed, individually and as parent and natural guardian and personal rep-

resentative of estate of Sule Mohammed, minor, deceased

Mallam Nasiru, individually and as parent and natural guardian and personal representative of estate of Yusif Nasiru, minor, deceased

Yusuf Musa, individually and as parent and natural guardian and personal representative of estate of Nafisatu Musa, minor, deceased

Mallam Muritala, individually and as parent and natural guardian and personal representative of estate of Umaru Muritala, minor, deceased

Mallam Tanko, individually and as parent and natural guardian and personal representative of estate of Madina Tankol, minor, deceased

Mallam Sheu, individually and as parent and natural guardian and personal representative of estate of Madina Tankol, minor, deceased

Malam Kabiru Mohamed, individually and as parent and natural guardian and personal representative of estate of Kabiru Mohamed, minor, deceased

Mallam Sule Abubakar, individually and as parent and natural guardian and personal representative of estate of Fatima Abubaker, minor, deceased

Mallam Idris, individually and as parent and natural guardian and personal representative of estate of Baba Idris, minor, deceased

Mallam Mohamed Bashir, individually and as parent and natural guardian and personal representative of estate of Sani Bashir, minor, deceased

Ibrahim, individually and as parent and natural guardian and personal representative of estate of Hassan Ibrahim, minor, deceased

Alhaji Shuaibu, individually and as parent and natural guardian and personal representative of estate of Masjbatu Shuaibu, minor, deceased

Mallam Abdullahi Sale, individually and as parent and natural guardian and personal representative of estate of Shamisiya Sale, minor, deceased

Mallam Ibrahim Amyarawa, individually and as parent and natural guardian and personal representative of estate of Yahaya Ibrahim, minor, deceased

Mallam Abdu Abubaker, individually and as parent and natural guardian and personal representative of estate of Nasitu Abubaker, minor, deceased

Mallam Yusuf, individually and as parent and natural guardian and personal representative of estate of Hodiza Yusuf, minor, deceased

Mallam Dauda Yusuf, individually and as parent and natural guardian and personal representative of estate of Abubaker Sheu, minor, deceased

Maliam Mohammed Sheu, individually and as parent and natural guardian and personal representative of estate of Mustapha Yakubu, minor, deceased

Alhaji Ubah, individually and as parent and natural guardian and personal representative of estate of Maryam Ubah, minor, deceased

Mallam Mohamadu Jabbo, individually and as parent and natural guardian of Auwalu Mohamadu

Mallam Abdullah Adamu, individually and as parent and natural guardian and personal representative of estate of Abdullah Adamu, minor, deceased

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IN THE

# Supreme Court of the United States

No. 08-___

PFIZER INC.,

*Petitioner*,

v.

RABI ABDULLAHI, *et al.*,

*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## PETITION FOR A WRIT OF CERTIORARI

Petitioner, Pfizer Inc. ("Pfizer"), respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit in this case.

## OPINIONS BELOW

The opinion of a divided panel of the Second Circuit (Pet. App. 1a-106a) is reported at 562 F.3d 163. One opinion of the district court (Pet. App. 114a-152a) is available at 2005 WL 1870811, and a second opinion of the district court (Pet. App. 153a-174a) is reported at 399 F. Supp. 2d 495.

## JURISDICTION

The Second Circuit issued its decision on January 30, 2009. Pet. App. 6a. Pfizer's petition for rehearing and rehearing *en banc* was denied on April 9, 2009. Pet. App. 112a. This Court has jurisdiction under 28 U.S.C. 1254(1).

## STATUTORY PROVISION INVOLVED

The Alien Tort Statute ("ATS"), 28 U.S.C. 1350, provides: "The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."

## STATEMENT

In the decision below, the Second Circuit dramatically expanded ATS jurisdiction by allowing two complaints to proceed against an American corporation for conducting a clinical trial of an antibiotic medication in Nigeria, allegedly without obtaining adequate consent as required by international law. In so doing, the Second Circuit disregarded this Court's caution in *Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 727 (2004), that there should be a "high bar to new private causes of action" under the ATS. The Second Circuit also created two circuit conflicts: (1) its decision sets a much lower bar for alleging state action under the ATS than the Fifth, Ninth, and Eleventh Circuits have required; and (2) its decision takes a much broader view than the Sixth, Ninth, Tenth, and Eleventh Circuits have taken of the kinds of ATS causes of action that may proceed against purely private actors. This Court should grant certiorari to resolve these conflicts and to give much-needed guidance to the lower courts in the appli-

cation of *Sosa* to ATS lawsuits against American corporations that do business abroad.

1. In 1996, Pfizer administered the new antibiotic Trovan to children in Kano, Nigeria, in the midst of an unprecedented outbreak of cerebospinal meningitis ("CSM"). Trovan had been tested previously in thousands of adult patients. In administering the medicine to ill children, Pfizer allegedly failed to advise that some would receive Trovan, and others (a control group) would receive an established comparator treatment. Pfizer also allegedly failed to advise of possible risks associated with either type of treatment, and to provide fully adequate care.

2. Respondents, allegedly participants in the clinical trial and/or their representatives, filed suits in two federal district courts invoking ATS jurisdiction. In August 2001, one set of respondents (*Abdullahi et al.*) filed suit in the U.S. District Court for the Southern District of New York, alleging that Pfizer's clinical trial violated international law.[1] In November 2002, a second set of respondents (*Adamu et al.*) filed suit in the U.S. District Court for the District of Connecticut, alleging jurisdiction under the ATS on grounds of international law as well as under two Connecticut state statutes. The *Adamu* action was transferred to the Southern District of New York and consolidated with the *Abdullahi* action.

The complaints, although lengthy, each made only a few brief references to the Nigerian govern-

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[1] The *Abdullahi* case was initially dismissed on the ground of *forum non conveniens*, *Abdullahi* v. *Pfizer, Inc.*, No. 01 Civ. 8118 (WHP), 2002 WL 31082956, at *12 (S.D.N.Y. Sept. 17, 2002), but that dismissal was vacated and remanded for further fact-finding, 77 Fed. Appx. 48, 53 (2d Cir. 2003).

ment's supposed assistance to Pfizer. The *Abdullahi* complaint alleged that the Nigerian government "provid[ed] the requisite request for a clinical trial letter to the FDA," and "arrang[ed] for Pfizer's accommodation in Kano." ¶108 & n.6 (Pet. App. 237a). The *Adamu* complaint alleged that "the Nigerian dictatorship at the time was intimately involved and contributed, aided, assisted and facilitated Pfizer's efforts to conduct the Trovan test," ¶ 21 (Pet. App. 312a), and that the "Nigerian government acted in concert with Pfizer by ... assigning Nigerian physicians to assist in the project," ¶ 6(h) (Pet. App. 299a). Neither complaint, however, alleged any specific facts that would support an inference that the Nigerian government knew of or participated in the specific conduct alleged to violate international law, namely Pfizer's supposed failure to obtain adequately informed consent to Trovan's administration.[2]

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[2] Plaintiffs' only other allegations of state involvement were similarly vague and general. For example, plaintiffs alleged that the Nigerian government silenced critics of the drug trial. *E.g.*, *Adamu* ¶¶ 6(h), 40 (Pet. App. 299a, 321a); *Abdullahi* ¶¶ 108 n.6, 147 (Pet. App. 237a, 252a). But plaintiffs did not allege that such critics were specifically addressing the administration of Trovan without adequate consent. Moreover, both complaints describe "silencing" as mere self-censorship by the critics out of a sense that the Nigerian dictatorship then in power would not tolerate public criticism, not as an active tactic by that regime.

Plaintiffs also alleged that, in response to a 1997 FDA audit, a letter from the ethics committee at the hospital where the clinical trial was held, stating that it had "reviewed Pfizer's test plans," was back-dated. *Abdullahi* ¶ 133 (Pet. App. 244a). But even if the committee were a state actor (which is not alleged) and even if such a letter was later created and back-dated, this allegation does not suggest that the Nigerian government, *at the*

3. The district court (Pauley, J.) dismissed the *Abdullahi* action for lack of subject matter jurisdiction under the ATS, reasoning that "[a] cause of action for Pfizer's failure to get any consent, informed or otherwise, before performing medical experiments on the subject children would expand customary international law far beyond that contemplated by the ATS." Pet. App. 141a (internal quotation marks omitted). Several months later, the district court dismissed the *Adamu* action based on the same reasoning. Pet App. 163a.[3]

4. A divided panel of the Second Circuit reversed. The panel majority (Parker, J., joined by Pooler, J.) held that a clinical trial conducted without adequate consent violates eight supposed sources of customary international law: (1) the International Covenant on Civil and Political Rights ("ICCPR"), (2) a 1997 Council of Europe convention, (3) a 2001 directive of the European Parliament, (4) a 2005 UNESCO declaration, (5) the Declaration of Helsinki issued by the World Medical Association, (6) the International Ethical Guidelines for Research Involving Human Subjects promulgated by the Council for International Organizations for Medical Sciences, (7) several countries' domestic laws, and (8) the Nuremberg Code. Pet. App. 26a-43a. The panel majority further concluded that these sources of a norm against nonconsensual clinical trials were "sufficiently specific,

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*time of the Trovan trial*, knew of or participated in the alleged lack of informed consent.

[3] The district court held, in the alternative, that the actions should be dismissed for *forum non conveniens*, finding that Nigeria was an adequate alternative forum. Pet. App. 170a. Pfizer did not rely on *forum non conveniens* as a basis for affirmance on appeal.

universally accepted, and obligatory for courts to recognize a cause of action to enforce the norm" within the meaning of the ATS. Pet. App. 49a.

The panel majority devoted only three paragraphs of its opinion to the question of state action. Starting from the premise that "a private individual will be held liable under the ATS if he 'acted in concert with' the state, i.e., 'under color of law,'" Pet. App. 50a, the panel majority found state action adequately pleaded, noting respondents' allegations "that the Nigerian government provided a letter of request to the FDA to authorize the export of Trovan, arranged for Pfizer's accommodations in Kano, and facilitated the nonconsensual testing." Pet. App. 50a-51a.

The panel majority suggested, in the alternative, that administering a clinical trial without adequate consent would give rise to a cause of action under the ATS even if brought against a purely private actor without any state involvement. The majority held that Pfizer is bound by the Nuremberg Code principle that "[t]he voluntary consent of the human subject is absolutely essential," Pet. App. 21a, even though that principle was announced as a result of criminal verdicts against state actors who were part of the governmental machinery of the Third Reich (the one non-state defendant tried at Nuremberg was acquitted), see Pet. App. 92a n.17 (dissent). And the majority held that Article 7 of the ICCPR, which provides that "no one shall be subjected without his free consent to medical or scientific experimentation," is "not limited to state actors; rather, it guarantees individuals the right to be free from nonconsensual medical experimentation by any entity—state actors, private actors, *or* state and private actors behaving in concert." Pet App. 32a, 33a (emphasis added).

Accordingly, the panel majority reversed and remanded for further proceedings in the district court.[4]

5. Judge Wesley dissented. Pet. App. 58a-106a. Judge Wesley rejected the majority's holding that there is any international law norm at all, enforceable against either a state or private actor, proscribing clinical trials lacking adequate consent. Pet. App. 60a-61a. Judge Wesley explained why such a norm is not "universal and obligatory":

> (1) the International Covenant on Civil and Political Rights has been described by the Supreme Court as a "well-known international agreement[] that despite [its] moral authority, ha[s] little utility," in defining international obligations, *Sosa*, 542 U.S. at 734, and moreover, it does not apply to private actors, such as the Defendant in this action;
>
> (2) the Council of Europe's Convention on Human Rights and Biomedicine—a regional convention—was not ratified by the most influential nations in the region, such as France, Germany, Italy, the Netherlands and the United Kingdom, and it was promulgated ... one year *after* the conduct at issue in this litigation;
>
> (3) the UNESCO Universal Declaration of Bioethics and Human Rights of 2005 and (4) the European Parliament Clinical Trial Directive of

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[4] After the Second Circuit denied Pfizer's petition for rehearing and rehearing *en banc*, Pfizer filed a motion in the Second Circuit requesting that the court stay its mandate pending the disposition of Pfizer's petition for a writ of certiorari. That motion was granted July 7, 2009.

> 2001 both also post-date the relevant time period by several years;
>
> (5) the Declaration of Helsinki issued by the World Medical Association, a private entity, and
>
> (6) the International Ethical Guidelines for Research Involving Human Subjects promulgated by the Council for International Organizations for Medical Sciences, another private entity, "express[] the sensibilities and the asserted aspirations of some countries or organizations" but are not "statements of universally-recognized legal obligations," *Flores* [v. *S. Peru Copper Corp.*, 414 F.3d 233,] 262 [(2d Cir. 2003)];
>
> (7) states' domestic laws, which, unsupported by express international accords, are not "significant or relevant for purposes of customary international law," *id.* at 249; and
>
> (8) the so-called Nuremberg Code, a statement of principles that accompanied a criminal verdict, possesses at best "subsidiary" value as a judicial decision, Statute of the International Court of Justice art. 38, June 26, 1945, 59 Stat. 1031, 33 U.N.T.S. 993.

Pet. App. 60a-61a (ellipsis and final two brackets added).

Judge Wesley went on to conclude that, "even assuming, for argument's sake, that international law prohibits states from conducting non-consensual medical tests," Pet. App. 98a, respondents had failed sufficiently to allege that Pfizer was acting in concert with *Nigeria*'s violation of international law. As Judge Wesley stated, "it is not enough ... for a plaintiff to plead state involvement in *some activity* of

the institution alleged to have inflicted injury upon a plaintiff; rather, the plaintiff must allege that the state was involved with the *activity that caused the injury* giving rise to the action." Pet. App. 101a (internal quotation marks omitted; emphasis and ellipsis in original). Judge Wesley noted that the complaints alleged that the Nigerian government provided general assistance, such as "request[ing] the import of Trovan and arrang[ing] for Pfizer's accommodations and some medical staff in Kano," but explained that the complained-of "activity was not, as the majority concludes, conducting the Trovan trials in general, but rather administering the drug without informed consent"—an activity in which the Nigerian government was nowhere alleged to have knowingly participated. Pet. App. 102a.

Judge Wesley also rejected the panel majority's alternative holding that an ATS claim might be brought against a private actor, even in the absence of state action, for engaging in a clinical trial without fully informed consent. He explained that, while the list of actionable international norms remains narrow as against state actors, it is narrower still against "private actors." Pet. App. 84a; see also Pet. App. 93a (quoting *Sosa*, 542 U.S. at 729).

6. During the pendency of the proceedings below, the Nigerian and Kano State governments themselves filed civil and criminal actions in Nigerian courts against Pfizer for conducting the Trovan trial in Kano. See Pet. App. 52a; *Nigeria Sues Drugs Giant Pfizer*, BBC News Online, June 5, 2007, *available at* http://news.bbc.co.uk/2/hi/africa/6719141.stm (last accessed July 1, 2009). These actions were premised on the governments' view that, far from knowingly participating with Pfizer in the clinical

trial, they were themselves harmed by Pfizer's actions and entitled to recover against Pfizer.

## REASONS FOR GRANTING THE WRIT

In the decision below, the Second Circuit announced for the first time that a private actor's clinical trial of a medication abroad, allegedly without obtaining adequate consent in the foreign country, is an international law violation enforceable in a U.S. court under the ATS. This decision conflicts with the decisions of other circuits both as to the nature of the state action required to sustain an ATS claim and the scope of customary international law enforceable under the ATS against a purely private actor. Certiorari should be granted to resolve these conflicts and to give much-needed guidance to the lower courts as to the limited circumstances under which ATS liability is available against American corporations that do business abroad.

The ATS, 28 U.S.C. 1350, provides: "The district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." This Founding-era statute "was originally understood to be available to enforce a small number of international norms," *Sosa*, 542 U.S. at 729, that are "specific, universal, and obligatory," *id.* at 732 (internal quotation marks omitted), such as "violation of safe conducts, infringement of the rights of ambassadors, and piracy," *id.* at 715 (citing Blackstone, 4 Commentaries 68).

In *Sosa*, this Court instructed the lower courts to exercise "vigilant doorkeeping" to ensure that this narrow list is not unduly expanded. 542 U.S. at 729; see *id.* at 720 ("Congress intended the ATS to furnish

jurisdiction for a relatively modest set of actions alleging violations of the law of nations."). The Court also urged caution in deciding "whether international law extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the defendant is *a private actor such as a corporation or individual*," as opposed to a state actor to whom international law norms generally apply. *Id.* at 732 n.20 (emphasis added). As Justice Breyer noted, an international law norm enforceable under the ATS "must have a content as definite" and universal as 18th-century norms such as the prohibition of piracy and also "must extend liability to *the type of perpetrator (e.g., a private actor)* the plaintiff seeks to sue." *Id.* at 760 (Breyer, J., concurring) (emphasis added).

But in the five years since *Sosa*, the lower courts have too often, as here, disregarded this Court's admonitions. The ATS has continued to be used to bring complaints for supposed misconduct that, as here, is a far cry from the settled paradigms Congress recognized at the Founding. The Second Circuit's decision, like its previous decision in the South African apartheid case, *Khulumani* v. *Barclay National Bank Ltd.*, 504 F.3d 254 (2d Cir. 2007), *aff'd for lack of quorum sub nom. American Isuzu Motors, Inc.* v. *Ntsebeza*, 128 S. Ct. 2424 (2008), acknowledges *Sosa* but in fact dramatically expands ATS jurisdiction over private American corporations doing business abroad. Recusals prevented the Court from deciding on the petition in *American Isuzu* and thus from providing urgently needed guidance on the scope of corporate secondary liability under the ATS. This petition presents a similar opportunity to clarify the scope of ATS liability as to American corporations doing business abroad and to dispel confusion on

questions that have bedeviled the lower courts in *Sosa*'s aftermath.

Certiorari should be granted, *first*, because the decision below conflicts with the decisions of other circuits as to both interpretation of ATS state action requirements and interpretation of *Sosa*'s limits on the scope of customary international law norms enforceable against private actors. Certiorari should be granted, *second*, because the scope of ATS liability against private actors for novel customary international law claims like the one here is a question of national and international importance. Where, as here, American corporations are haled into U.S. courts to face foreign regulatory or tort claims in the guise of international law violations, the ATS threatens to become an ever more expansive vehicle for burdensome litigation and crippling liability that imposes a kind of discriminatory tax on American companies doing business abroad.

## I. THE SECOND CIRCUIT'S DECISION EXPANDING ATS JURISDICTION IS IN TENSION WITH THIS COURT'S DECISION IN *SOSA* AND CONFLICTS WITH DECISIONS OF OTHER CIRCUITS

This Court should grant certiorari to resolve two circuit conflicts created by the decision below: (1) a conflict concerning the degree of state action required to allow an ATS complaint to proceed, and (2) a conflict concerning what kinds of international law norms may be pleaded under the ATS against purely private actors.

The law of nations, as its name suggests, has historically required fidelity by nation-states, not by private individuals. There is no general inter-

national common law of torts. Thus, to establish subject matter jurisdiction under the ATS for a violation of international law by a private corporation or individual, plaintiffs in most cases must allege that the private actor acted under color of law or in concert with a foreign government.

The Second Circuit's decision, however, conflicts with decisions of other circuits as to the degree of state action required to transform a private party into a state actor for ATS purposes. The Fifth, Ninth, and Eleventh Circuits all have rejected ATS complaints that were based on purported state action but that failed to allege that the foreign government knew of or participated in the *specific conduct* alleged to violate international law. The Second Circuit, by contrast, held below that respondents had sufficiently alleged state action merely by referring to the Nigerian government's general assistance to Pfizer without any allegation that the government knew of or participated in Pfizer's alleged failure to obtain adequate consent to the clinical trial of Trovan. This holding conflicts with the decisions of other circuits that have found state action adequately invoked only by allegations that the state was specifically involved in the allegedly wrongful conduct, either as a matter of official state policy or under color of law.

The Second Circuit created an additional circuit conflict by its alternative holding that an ATS claim may proceed, even without any state action, against a private corporation for failure to obtain adequate consent to a clinical trial. The Sixth, Ninth, Tenth, and Eleventh Circuits all have held that ATS jurisdiction over purely private actors is limited to an exceedingly narrow category of offenses of universal concern—namely, war crimes, genocide, slave trade,

and piracy. Those circuits accordingly have required ATS claims against private actors to be dismissed where they allege violation of other international law norms—even norms against such offenses as rape, torture, abduction, detention, pesticide poisoning, and other alleged crimes against humanity. As Judge Wesley noted in dissent, the majority's recognition of a "previously unrecognized norm of international law" against nonconsensual clinical trials "apparently overlook[s] the fact that this purported norm in no way resembles those few norms enforceable against private entities." Pet. App. 92a-93a. This Court should grant certiorari to resolve both conflicts.

### A. The Second Circuit's Decision Conflicts With Decisions Of Other Circuits As To The Degree Of State Action Required For An ATS Claim

The Second Circuit's decision allows respondents to proceed with their ATS claims despite their failure to allege that the Nigerian government knew of or participated in the specific conduct by Pfizer that is claimed to violate international law—namely, the administration of a clinical trial without adequate consent. Discussing the requirement of state action in barely three paragraphs of its opinion, Pet. App. 50a-52a, the Second Circuit allowed the complaints to survive based merely on cursory allegations of general assistance by the Nigerian government. See *supra* at 3-5 & n.2.

No other circuit has so permissively interpreted the degree of state action required to make out violations of international law cognizable under the ATS. To the contrary, the vague, conclusory, and general allegations of state assistance allowed by the Second Circuit here would have led to dismissal under the

conflicting standards for state action applied under the ATS in the Fifth, Ninth, and Eleventh Circuits. As Judge Wesley explained in dissent, "it is not enough ... for a plaintiff to plead state involvement in *some activity* of the institution alleged to have inflicted injury upon a plaintiff; rather, the plaintiff must allege that the state was involved with the *activity that caused the injury* giving rise to the action." Pet. App. 101a (internal quotation marks omitted; emphasis and ellipses in original).[5]

The Ninth Circuit's decision in *Abagninin* v. *AMVAC Chemical Corp.*, 545 F.3d 733 (9th Cir. 2008), starkly illustrates this circuit conflict. In *Abagninin*, an ATS complaint was brought against a private company that managed an agricultural plantation in the Ivory Coast, claiming that the company's use of a pesticide that caused sterilization of plantation workers had amounted to a crime against humanity in violation of customary international law. The complaint alleged collaboration between the Ivory Coast government and the private company.

The Ninth Circuit, however, found the allegations in *Abagninin* insufficient to establish state action because they did not identify any knowing participation by the Ivory Coast government in the specific conduct complained of: the use of the harmful pes-

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[5] Allowing such conclusory allegations to proceed not only creates a circuit conflict with other courts of appeals interpreting the state action requirements of the ATS, but also is in tension with this Court's recent decision in *Ashcroft* v. *Iqbal*, 129 S. Ct. 1937 (2009), which held, extending the holding in *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544 (2007), that a pleading is insufficient under Fed. R. Civ. P. 8(a)(2) "where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct." 129 S. Ct. at 1950.

ticide. The Ninth Circuit explained that not just "any involvement by the State meets the 'State action' requirement"; rather, "allegations of 'affirmative action by the government of the Ivory Coast' fail to state a claim for crimes against humanity because Abagninin does not allege that the use of [the pesticide] was part of a *[state] plan or policy* to commit one of the enumerated acts, *i.e.* to sterilize the plantation workers." *Id.* at 742 (emphasis added). Cf. *Sosa*, 542 U.S. at 737 (noting that the plaintiff there failed to allege any "'*state policy*'" favoring prolonged arbitrary detention) (quoting RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 702 (1986)) (emphasis added).

The Eleventh Circuit, like the Ninth Circuit, has required dismissal of ATS claims lacking in specificity as to a foreign government's involvement in the alleged violation of international law. In determining the existence of state action under the ATS, the Eleventh Circuit "look[s] to ... 'jurisprudence under 42 U.S.C. § 1983,'" *Aldana* v. *Del Monte Fresh Produce, N.A., Inc.*, 416 F.3d 1242, 1247 (11th Cir. 2005) (quoting *Kadic* v. *Karadzic*, 70 F.3d 232, 245 (2d Cir. 1995)), and thus asks whether a defendant has acted "under color of law."[6]

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[6] To the extent that the ATS requires a showing of action "under color of law" analogous to that under 42 U.S.C. 1983, the Second Circuit's decision is also in tension with that of many other circuits interpreting the latter statute. For example, the First Circuit has held that, "to the extent that state-granted authority can justify a finding of state action, that authority must be connected to the aim of encouraging or compelling *the specific complained-of conduct*." *Barrios-Velazquez* v. *Asociacion de Empleados del Estado Libre Asociado de Puerto Rico*, 84 F.3d 487, 493 (1st Cir. 1996) (emphasis added). The Fifth Circuit has explained that, "[t]o make the requisite showing of

In *Aldana*, the Eleventh Circuit affirmed the dismissal of all but one ATS claim alleging state action by Guatemala in connection with militias' violent disruption of labor organizing activities at an American company's plant. The court there found that allegations that Guatemala broadly tolerated private militias and that Guatemalan police failed to stop the violence were inadequate to support state action where the plaintiffs "d[id] not allege sufficient facts to warrant the inference that the National Police knew of and purposefully turned a blind eye to the events" that were the specific conduct alleged to violate international law. 416 F.3d at 1248.

In *Romero* v. *Drummond Co.*, 552 F.3d 1303 (11th Cir. 2008), the Eleventh Circuit similarly affirmed a rejection of claims under the Torture Victim Protection Act, 28 U.S.C. 1350 note ("TVPA"), for failure to prove state action with sufficient specificity. Because the TVPA expressly requires a showing of action "under color of law," the Eleventh Circuit, as in ATS cases like *Aldana*, looked to "under color of law" jurisprudence under 42 U.S.C. 1983, see 552 F.3d at 1317 (relying on *Brentwood Academy*, 531 U.S. at 295).

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state action by a regulated entity, [a plaintiff] must establish 'a sufficiently close nexus between the State and the *challenged action* of the regulated entity.'" *Cornish* v. *Correctional Servs. Corp.*, 402 F.3d 545, 550 (5th Cir. 2005) (quoting *Blum* v. *Yaretsky*, 457 U.S. 991, 1004 (1982)). And in *Crissman* v. *Dover Downs Entertainment Inc.*, 289 F.3d 231 (3d Cir. 2002) (*en banc*), the Third Circuit explained that the "central purpose" of the state action inquiry is to "'assure that constitutional standards are invoked when it can be said that the State is *responsible* for the *specific conduct* of which the plaintiff complains.'" *Id.* at 239 (quoting *Brentwood Academy v. Tennessee Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 295 (2001)) (emphasis altered).

Applying that standard, the court upheld summary judgment against plaintiffs, rejecting their attempt to assert state action where executives of a Colombian subsidiary of an American coal mining company allegedly paid paramilitary operatives to torture and assassinate leaders of a Colombian trade union. The Eleventh Circuit held that, to satisfy the requirement of state action, "there must be proof of a symbiotic relationship between a private actor and the government that involves the [misconduct] alleged in the complaint." 552 F.3d at 1317. Finding insufficient the complaint's allegations of a general relationship between the military and the private paramilitary actors, *id.* at 1317-18, the court held that "plaintiffs failed to offer evidence either that state actors were actively involved in the assassination of the union leaders or that the paramilitary assassins enjoyed a symbiotic relationship with the military for the purpose of those assassinations." *Id.* at 1318.

The Fifth Circuit approved a similar approach to that of the Ninth and Eleventh Circuits in affirming the dismissal of an ATS complaint in *Beanal* v. *Freeport-McMoRan, Inc.*, 969 F. Supp. 362, 374-80 (E.D. La. 1997), *aff'd*, 197 F.3d 161 (5th Cir. 1999), a case emphasized by Judge Wesley in his dissent from the panel majority's state action holding. As Judge Wesley noted, Pet. App. 103a, *Beanal* held that an ATS complaint does not adequately allege state action unless a governmental actor is alleged to have actually participated in the wrongdoing at issue.

In sharp contrast to these decisions by other circuits, the Second Circuit allowed plaintiffs' complaints to survive dismissal even though, as Judge Wesley's dissent noted, they "do not allege that the

government or any government employee played any role in either administering Trovan without consent or deciding to do so in the first instance," but rather "[a]t most ... alleg[e] that the Nigerian government acquiesced to or approved the Trovan program in general without knowing" its details. Pet. App. 102a, 105a. The decision below thus conflicts with previous interpretations of the state action requirement under the ATS (and TVPA) by other circuits, whether those circuits require a showing of official state policy as in the Ninth Circuit's decision in *Abagninin* and Restatement (Third) of Foreign Relations Law § 702, or action under color of law as in the Eleventh Circuit's decisions in *Aldana* and *Romero*. This Court should grant certiorari in order to resolve this split and to clarify the appropriate standard for assessing allegations of state action under the ATS.

### B. The Second Circuit's Decision Conflicts With Decisions Of Other Circuits As To The Scope Of Customary International Law Norms Applicable To Purely Private Actors

Certiorari is equally required if the Second Circuit decision is understood alternatively to expand ATS jurisdiction over purely private actors. This Court's decision in *Sosa* admonishes the lower courts to engage in "vigilant doorkeeping" against improper uses of ATS jurisdiction. 542 U.S. at 729. *Sosa* cautioned that the "federal courts should not recognize private claims under federal common law for violations of any international law norm with less definite content and acceptance among civilized nations than the historical paradigms familiar when § 1350 was enacted." *Id.* at 732.

Such "vigilan[ce]" should be all the more heightened when the defendant is a private actor lacking any particularized involvement with foreign state action or policy. Because the law of nations typically binds nation states, not private actors, ATS jurisdiction must be especially sparing when "the perpetrator being sued ... is a private actor such as a corporation or individual." *Sosa*, 542 U.S. at 732 n.20. The Restatement (Third) of Foreign Relations Law, for example, distinguishes, for purposes of universal jurisdiction, between "those violations that are actionable when committed by a state and a more limited category of violations" that are actionable against private actors. *Kadic*, 70 F.3d at 240 (citing RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW §§ 404, 702). The latter category consists only of "certain offenses recognized by the community of nations as of universal concern, such as piracy, slave trade, attacks on or hijacking of aircraft, genocide, war crimes, and perhaps certain acts of terrorism." RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 404.

The Second Circuit's decision disregarded *Sosa*'s admonitions on both counts. To begin with, it departed from all precedent in recognizing a novel private right of action under supposed customary international law against conducting a clinical trial without fully informed consent. Of the eight sources of customary international law relied upon by the panel majority, seven are patently insufficient to provide a private cause of action under the ATS: Three post-date the 1996 Trovan trial,[7] two are pure-

[7] The 1997 Council of Europe Convention, the 2001 directive of the European Parliament and the 2005 UNESCO declaration by definition arise too late to assist the plaintiffs here. *See Vietnam Ass'n for Victims of Agent Orange* v. *Dow Chem. Co.*,

ly aspirational,[8] one is purely domestic,[9] and one has been rejected by this Court as unhelpful in the ATS context.[10] The panel thus relied principally on an eighth source, the Nuremberg Code, see Pet. App. 79a, but that source too is insufficient.

Numerous federal decisions in other contexts have held that "'there is no private right of action for an alleged violation of international law for the protection of human research subjects under ... the Nuremberg Code.'" *Ammend* v. *Bioport*, 322 F. Supp. 2d 848, 872 (W.D. Mich. 2004) (quoting *Robertson* v. *McGee*, No. 01-cv-60, 2002 WL 535045, *3 (N.D. Okla. Jan. 28, 2002)). See, *e.g.*, *White* v. *Paulsen*, 997 F. Supp. 1380, 1383 (E.D. Wash. 1998) (declining "to

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517 F.3d 104, 118 (2d Cir. 2008) (treaty ratified in 1975 could not be used to assess conduct in the 1960s); *Abagninin*, 545 F.3d at 738 ("A treaty not ratified by the United States at the time of the alleged events cannot form a basis for an ATS claim.").

[8] The Declaration of Helsinki and the International Ethical Guidelines for Research Involving Human Subjects do not constitute "statements of universally-recognized legal obligations." *Flores*, 414 F.3d at 262.

[9] The fact that many countries' domestic laws require informed consent in clinical drug trials does not give those laws the status of customary international law. *See, e.g., IIT* v. *Vencap*, 519 F.2d 1001, 1015 (2d Cir. 1975) (Friendly, J.) (mere fact that every nation's municipal law may prohibit theft does not incorporate the Eighth Commandment "Thou Shalt not steal" into the law of nations).

[10] This Court has stated that the ICCPR has "little utility" for ATS purposes, *Sosa*, 542 U.S. at 734-35, and the courts of appeals have uniformly held that it "does not provide independent, privately enforceable rights," *Guaylupo-Moya* v. *Gonzales*, 423 F.3d 121, 133 (2d Cir. 2005). *Accord Padilla-Padilla* v. *Gonzales*, 463 F.3d 972, 979-80 (9th Cir. 2006); *Igartua-De La Rosa* v. *United States*, 417 F.3d 145, 150 (1st Cir. 2005) (*en banc*).

imply from the law of nations the existence of a private right of action" for alleged violations of the prohibition on nonconsensual medical experimentation). Cf. *Conway* v. *A.I. DuPont Hosp. for Children*, No. 04-4862, 2007 WL 560502, at * 7 (E.D. Pa. Feb. 14, 2007) (agreeing with "[c]ourts [that] have held that there is no private right of action for violations of these declarations, codes, reports, or regulations," specifically the Nuremberg Code); *Hoover* v. *W. Va. Dep't of Health & Human Servs.*, 984 F. Supp. 978, 980 (S.D. W. Va.), *aff'd*, 129 F.3d 1259 (4th Cir. 1997) ("[T]he Helsinki Accord does not create a private right of action in U.S. federal courts and [does] not have the force of law."); *Jaffee* v. *United States*, 663 F.2d 1226 (3d Cir. 1981) (*en banc*) (rejecting an analogy to the Nuremberg Code in denying state-law and federal due process claims based on the government's testing of the effects of radiation on unknowing soldiers).

The decision below departs from that previously unbroken line of precedents by permitting a party to premise a cause of action on an alleged violation of the Nuremberg Code. The Second Circuit's bold expansion of ATS jurisdiction thus disregards this Court's admonition in *Sosa* that there should be a "high bar to new private causes of action" under the ATS, 542 U.S. at 727, and that federal courts "have no congressional mandate to seek out and define new and debatable violations of the law of nations," *id.* at 728.

Even if the Nuremberg Code (or any of the Second Circuit's other asserted sources of customary international law) could give rise to an international law claim against a foreign government, however, the Second Circuit created a clear conflict with other

circuits in allowing such a novel claim to be asserted against a purely private actor. Administering a clinical trial without fully informed consent is a matter customarily governed by domestic administrative or tort law, and bears no resemblance to the narrow category of activities—war crimes, slave trade, piracy, or genocide—as to which international law norms have been held enforceable against purely private actors.

In conflict with the decision below, other circuits have repeatedly held that torts outside this narrow category are actionable under the ATS only against state, not purely private actors:

In *Cisneros* v. *Aragon*, 485 F.3d 1226 (10th Cir. 2007), for example, the Tenth Circuit held that, in the absence of concerted state policy, even the commission of child rape and other forms of sexual violation are not international law violations actionable under the ATS against purely private actors. In so holding, the Tenth Circuit relied upon earlier authority from the Second Circuit: "A pre-*Sosa* circuit-court opinion reflected this limitation when it recognized ATS causes of action for war crimes and genocide [against private actors] but not 'torture and summary execution—when not perpetrated in the course of genocide or war crimes.'" *Id.* at 1231 (quoting *Kadic*, 70 F.3d at 243).

Similarly, in *Abagninin*, the Ninth Circuit held that manufacture and use of a deadly agricultural pesticide on a banana plantation was not actionable under the ATS absent state action. The court relied on "[t]he traditional conception regarding crimes against humanity," which is "that a policy must be present and must be that of a State, as was the case in Nazi Germany." 545 F.3d at 741 (citing *Prosecutor*

v. *Tadic*, IT-94-1-T, Judgment, ¶ 654 (May 7, 1997)); *see also id.* ("crimes against humanity are crimes committed through political organization"). Even though the pesticide was alleged to have caused serious injury and death, its administration was deemed insufficient to justify an ATS complaint against a purely private actor not acting under a state policy.

Likewise, in *Aldana*, the Eleventh Circuit held that arbitrary detention, alleged crimes against humanity, and interference with rights of association by private parties were not actionable under the ATS against a private corporate defendant where there was no state action. 416 F.3d at 1247; cf. *id.* ("State-sponsored torture, unlike torture by private actors, likely violates international law and is therefore actionable under the Alien Tort Act.")

And in *Taveras* v. *Taveraz*, 477 F.3d 767 (6th Cir. 2007), the Sixth Circuit held that even international child abduction and kidnapping were not cognizable as violations of international law under the ATS in the absence of state action. The court noted that "the ATS, by no means, supplies jurisdiction over every wrong committed against an alien." *Id.* at 771.

The majority below made no mention of these cases and did not try to reconcile them with its alternative holding. But, as Judge Wesley explained in dissent, the tort alleged here against Pfizer, "medical experimentation[,] more closely resembles the acts for which only state actors may be held responsible," and even "the norm against *torture* reaches only state actors." Pet. App. 90a (Wesley, J., dissenting) (emphasis added) (citing, *inter alia*, RESTATEMENT (THIRD) OF FOREIGN RELATIONS LAW § 702(d)).

Because the Second Circuit's decision announces a new norm untethered to *Sosa*'s criteria and disregards the crucial ATS distinction between customary international law violations asserted against state and private actors, certiorari is warranted. If an American corporation's clinical trial abroad is sufficient to give rise to a violation of international law warranting ATS jurisdiction, then it is difficult to see any limiting principle to prevent the ATS from supplanting domestic remedies and becoming a plenary international law of tort.

## II. THE SECOND CIRCUIT'S EXPANSION OF ATS JURISDICTION OVER AMERICAN CORPORATIONS DOING BUSINESS ABROAD RAISES ISSUES OF NATIONAL AND INTERNATIONAL IMPORTANCE

This Court instructed in *Sosa* that "the determination whether a norm is sufficiently definite to support a[n ATS] cause of action should (and, indeed, inevitably must) involve an element of judgment about the practical consequences of making that cause available to litigants in the federal courts." 542 U.S. at 733. The decision below will have significant adverse practical consequences for the conduct of private business abroad and for the Nation's foreign policy and commercial relations. These adverse consequences provide additional reasons why certiorari should be granted.

*First*, the expansion of corporate ATS liability exemplified by the Second Circuit's decision has the potential to subject American corporations doing business abroad to burdensome litigation, public relations problems, and crippling liability that will discourage their participation in international investment and development. See generally GARY CLYDE

HUFBAUER & NICHOLAS K. MITROKOSTAS, AWAKENING MONSTER: THE ALIEN TORT STATUTE OF 1789, at 37-43 (2003) (calculating the monetary damage to trade and foreign direct investment likely to be caused by increased ATS suits against corporations). Corporations doing business in foreign jurisdictions present attractive deep pockets and publicity magnets for plaintiffs seeking to bring ATS complaints. Because the allegations often turn on events occurring in the far corners of the developing world, with testimony and documents all in a foreign language, discovery is particularly burdensome. Additionally, the negative corporate publicity that flows from inflammatory allegations of international law violations enables plaintiffs to seek coercive settlements.

Such features may explain the noticeable increase in ATS cases against American corporations in the past decade. As commentators have noted, "In the latest wave of ATS litigation, foreign plaintiffs have sued corporations—primarily U.S. corporations—in U.S. courts seeking civil redress for violations of customary international human rights laws in non-U.S. countries." Jack L. Goldsmith & Alan O. Sykes, *Lex Loci Delictus & Global Economic Welfare: Spinozzi v. ITT Sheraton Corp.*, 120 HARV. L. REV. 1137, 1146 (2007). Such litigation tends to occur disproportionately against American corporations because "ATS-style tort suits by private parties to recover under customary international law are available only in the United States, and because U.S. personal jurisdiction laws apply much more easily to U.S. than to foreign firms." *Id.*; see also Melissa A. Waters, *Mediating Norms & Identity: The Role of Transnational Judicial Dialogue In Creating & Enforcing International Law*, 93 GEO. L.J. 487, 574 n.15 (2005) ("Human rights lawyers have successfully

utilized the Alien Tort Claims Act to bring a series of actions against foreign officials and, increasingly, against U.S. and foreign corporations for [alleged] human rights abuses committed abroad."); Armin Rosencranz & Richard Campbell, *Foreign Environmental & Human Rights Suits Against U.S. Corporations In U.S. Courts*, 18 STAN. ENVTL. L. J. 145, 148-71 (1999) (analyzing cases in which foreign plaintiffs brought suit against U.S. corporations in U.S. courts under the ATS).

ATS claims against American corporations thus pose a significant risk of vexatiousness, not unlike actions in other contexts that this Court has sought to restrain through the use of stringent pleading standards and narrow statutory construction. See, *e.g.*, *Ashcroft* v. *Iqbal*, 129 S. Ct. 1937; *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544; *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Dabit*, 547 U.S. 71, 86 (2006); *Dura Pharms., Inc.* v. *Broudo*, 544 U.S. 336, 347 (2005). This Court's review is necessary to prevent abuse of the ATS and to provide corporations with notice of the scope of their potential liability in U.S. courts for their purely private conduct occurring in foreign countries.

*Second*, the Second Circuit's decision implicates the foreign relations concerns that this Court identified in *Sosa*. See 542 U.S. at 727 (the federal courts should be "particularly wary of impinging on the discretion of the Legislative and Executive Branches in managing foreign affairs"). The Second Circuit's uniquely permissive state action standard allows ATS complaints to proceed based upon only the thinnest reed of alleged involvement by a foreign government. Such a lowered pleading standard for state action makes it easier to attribute bad acts

to foreign governments, causing needless offense to such governments if a greater number of such allegations survive dismissal.[11] The decision below thus presents the very real possibility of "embarrass[ing] the United States in the conduct of its foreign affairs, which is committed by the Constitution to the executive and legislative—the political—departments of the government." *Igartua-De La Rosa*, 417 F.3d at 151 (quoting *Oetjen* v. *Central Leather Co.*, 246 U.S. 297, 302 (1918)).

*Finally*, expansive construction of the ATS as in the decision below injures international commercial relations by tending to supplant measures for domestic redress. By authorizing a radical and unprecedented expansion of ATS jurisdiction to encompass the administration of a clinical trial by a U.S. corporation in a foreign nation, the decision below competes with domestic regulation by Nigeria and other nations through their own administrative and judicial systems. Under the decision below, any private doctor acting in any hospital in the world, even in the absence of any state action or policy, could be haled before a U.S. district court for failing to obtain "informed consent"—a term that is surely subject to varying definitions among different domestic law regimes. Domestic law and remedies, however, can better accommodate different nations' divergent interests with respect to the administration of medical treatment. And domestic courts are better equipped than American plaintiffs' lawyers to assess the rel-

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[11] This danger is illustrated here, where the Nigerian government itself has sued Pfizer over the Trovan clinical test, viewing itself as a victim entitled to compensation, at the same time as the complaints here cast aspersions on Nigeria for its supposed backing and facilitation of the test. See *supra* at 9-10.

ative costs and benefits of clinical trial practices for their nations.

These adverse practical consequences raise issues of national and international importance that provide additional reasons for this Court to review the Second Circuit's decision.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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July 8, 2009

# APPENDIX

# APPENDIX A

United States Court of Appeals,
Second Circuit.

Docket Nos. 05-4863-cv(L), 05-6768-cv(CON).

Rabi ABDULLAHI, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatau Abdullahi, Salisu Abullahi, individually and as the natural guardian and personal representative of the estate of his son Abulliahi [Manufi] Salisu, Alasan Abdullahi, individually and as the natural guardian and personal representative of the estate of his daughter Firdausi Abdullahi, Ali Hashimu, individually and as the natural guardian and personal representative of the estate of his daughter Suleiman, Muhammadu Inuwa, individually and as the natural guardian and personal representative of the estate of his son Abdullahi M. Inuwa, Magaji Alh Laden, individually and as the natural guardian and personal representative of the estate of his son Kabiru Isyaku, Alhaji Mustapha, individually and as the natural guardian and personal representative of the estate of his daughter Asma'u Mustapha, Suleiman Umar, individually and as the natural guardian and personal representative of the estate of his son Buhari Suleiman, Zainab Abdu, a minor, by her mother and natural guardian, Haja Abdullahi, Haji Abdullahi, individually, Firdausi Abdullahi, a minor, by her father and natural guardian Abdullahi Madawaki, Abdullahi Madawaki, individually, Sani Abdullahi, a minor, by his father and natural guardian, Sani Abdullahi, Abdullahi Ado, a minor, by his mother and natural guardian, Aisha Ado, Aisha Ado, individually, Ab-

dumajid Ali, a minor, by his father and natural guardian, Alhaji Yusuf Ali, Nura Muhammad Ali, a minor, by his father and natural guardian, Muhammad Ali, Muhammad Ali, individually, Umar Badamasi, a minor, by his father and natural guard-ian, malam Badamasi Zubairu, Malam Badamasi Zubairu, individually, Muhammadu Fatahu Danladi, a minor, by his father and natural guardian, Alhaji Danladi Ibrahim, Alhaji Danaldi Ibrahim, individually, Dalha Hamza, a minor, by his father and natural guardian malam Hamza Gwammaja, Malam Gwammaja, individually, Tasiu Haruna, a minor, by his guardian Mukhtar Saleh, Mukhtar Saleh, individually, Muhyiddeen Haasan, a minor, by his father and natural guardian, Tijjani Hassan, Tijjani Hassan, individually, Kawu Adamu Ibrahim, a minor, by his father and natural guardian, Malam Abamus Ibrahim Adamu, Alhaji Ibrahim Haruna, individually, Mallam Idris, individually, Yusuf Idris, a minor, by his father and natural guardian, Idris Umar, Idris Umar, individually, Hafsat Isa, a minor, by her father and natural guardian, Isa Muhammed Isa, Isa Muhammed Isa, individually, Taju Isa, a minor, by her father and natural guardian, Malam Isa Usman, Malam Isa Usman, individually, Hadiza Isyaku, a minor, by her father and natural guardian, Isyaki Shuaibu, Isyaku Shuaibu, individually, Zahra'u Jafaru, a minor, by her father and antural guardian, Jafru Baba, Jafaru Baba, individually, Anas Mohammed, a minor, by his father and natural guardian, Malam Mohammed, Malam Mohammed, individually, Nafisatu Muhammed, a minor, by her mother and natural guardian, Yahawasu Muhammed, Yahawasu Muhammed, individually, Muhsinu Tijjani, a minor, by his father and natural guardian,

Tijjani Hassan, Alhaji Yusuf Ali, Maryam Idris, a minor, by her father and natural guardian, Malam Idris, Ajudu Ismaila Adamu, individually and as parent and natural guardian of Yahaya Ismaica, minor, Malam Mohammed, individually and as parent and natural guardian of Bashir Mohammed, minor, Malam Yusab Ya'u Amale, individually and as parent and natural guardian of Suyudi Yusals Yu'a, minor, Malasm Haruna Adamu, individually and as parent and natural guardian of Mo-hammed Tasi'u Haruna, minor, Zangon Kwajalawa, individually and as parent and natural guardian of Nuruddim Dauda, minor, Malam Dahauru Ya'y, individually and as parent and natural guardian of Rabi Dahuru, minor and as parent and natural guardian of Zainab Musa Dahuru, minor, Zangon Marikita, individually and as parent and natural guardian of Ismaila Musa, minor, Arhaji Muihammad Soja, individually and as parent and natural guardian and personal representative of Estate of Hamaza Achaji Muhammad, minor, deceased, Achaji Ibrahim Dankwalba, individually and as parent and natural guardian of Personal Representative of Est of Abdullahi Ibrahim, minor, Mallam Lawan, individually and as parent and natural guardian and personal representative of Est. of Aisha Lawan, minor, deceased, Alhaji Muhammed Tsohon Sojo, individually and as parent and natural guardian and personal representative of Est. of Unni Alhasi Muhammed, minor, Ismaila Zubairui, individually and as parent and natural guardian and personal representative of Est. of Mustapha Zubairu, minor, Deceased, Abubaker Musa, individually and as parent and natural of Sa'adatu Musa, Minor, Mohamed Abdu, individually and as parent and natural guardian of Haruna Abdu, minor, Mallam Hassan,

individually and as parent and natural guardian and personal representative of Est. of Sadiya Hassan, minor, deceased, Mallam Yakubu Umar, individually and as parent and natural guardian of, Mallam Samaila, individually and as parent and natural guardian of Adamu Samalia, minor, Musa Yahaya, individually and as parent and natural guardian of Ukhasa Musa, minor, Audu Ismailia Adamu, individually and as parent and natural guardian of Yashaya Samaila, Malam Musa Dahiru, individually and as parent, Malam Musa Zango, individually and as parent and natural guardian os Samaila Musa, mi-nor, Mallam Alhassan Maihula, individually and as a parent and natural guardian of Najib Maihula, minor, Mallam Abdullah Gama, individually and as parent and natural guardian of Dankuma Gama, Minor, Dauda Nuhu, individually and as parent and natural guardian and personal representative of Est. of Hamisu Nuhu, minor, deceased, Mallam Abdullahi, individually and as parent and natural guardian and personal representative of Est. of Najaratu Adbullahi, minor, deceased, Malam Umaru Mohammed, individually and as parent and natural guardian and personal representative of Est. of Sule Mohammed, minor, deceased, Mallam Nasiru, individually and as parent and natural guardian and personal representative of Est. of Yusif Nasiru, minor, deceased, Yusuf Musa, individually and as parent and natural guardian and personal representative of Est. of Nafisatu Musa, minor, deceased, Mallam Muritala, individually and as parent and natural guardian and personal representative of Est. of Umaru Muritala, minor, deceased, Mallam Tanko, individually and as parent and natural guardian and personal representative of Est. of

madina Tankol, minor deceased, Mallam Sheu, individually and as parent and natural guardian and personal representative of Est. of Madina Tankol, minor, deceased, Malam Kabiru Mohamed, individually and as parent and natural guardian and personal representative of Est. of Kabiru Mohamed, minor, deceased, Mallam Sule Abubakar, individually and as parent and natural guardian and personal representative of Est. of Fatima Abubaker, minor, deceased, Mallam Idris, individually and as parent and natural guardian and personal representative of Est. of Baba Idris, minor, deceased, Mallam Mohamed Bashir, individually and as parent and natural guardian and personal representative of Est. of Sani Bashir, minor, deceased, Ibrahim, individually and as parent and natural guardian and personal representative of Est. Hassan Ibrahim, minor, deceased, Alhaji Shuaibu, individually and as parent and natural guardian and personal representative of Est. of Masjbatu Shuaibu, minor, deceased, Mallam Abdullahi Sale, individually and as parent and natural guardian and personal representative of Est. of Shamisiya Sale, minor, deceased, Mallam Ibrahim Amyarawa, individually and as parent and natural guardian and personal representative of Est. of Yahaya Ibrahim, minor, deceased, Mallam Abdu Abubaker, individually and as parent and natural guardian and personal representative of Est. of Nasitu Abubaker, minor, deceased, Mallam Yusuf, individually and as parent and natural guardian and personal representative of Est. of Hodiza Yusuf, minor, deceased, Mallam Dauda Yusuf, individually and as parent and natural guardian and personal representative of Est. of Abubaker Sheu, minor, deceased, Maliam Mohammed Sheu, individually and

as parent and natural guardian and personal representative of Est. of Mustapha Yakubu, minor, deceased, Alhaji Ubah, individually and as parent and natural guardian and personal representative of Est. of Maryam Ubah, minor, deceased, Mallam Mohamadu Jabbo, individually and as parent and natural guardian of Auwalu Mohamadu, Mallam Abdullah Adamu, individually and as parent and natural guardian and personal representative of Est. of Abdullah Adamu, minor,

Plaintiffs-Appellants,

v.

PFIZER, INC.,

Defendant-Appellee.

Argued: July 12, 2007.
Decided: Jan. 30, 2009.

Before: POOLER, B.D. PARKER, and WESLEY, Circuit Judges.

BARRINGTON D. PARKER, Circuit Judge:

This consolidated appeal is from the judgments of the United States District Court for the Southern District of New York (Pauley, J.) dismissing two complaints for lack of subject matter jurisdiction under the Alien Tort Statute, 28 U.S.C. § 1350 ("ATS"), and in the alternative, on the ground of *forum non conveniens*. Plaintiffs-Appellants Rabi Abdullahi and other Nigerian children and their guardians sued Defendant-Appellee Pfizer, Inc. under the ATS ("the *Abdullahi* action"). They alleged that Pfizer

violated a customary international law norm prohibiting involuntary medical experimentation on humans when it tested an experimental antibiotic on children in Nigeria, including themselves, without their consent or knowledge. Plaintiffs-Appellants Ajudu Ismaila Adamu and others, also children and their guardians who were part of Pfizer's Nigerian drug experiment, brought a similar action against Pfizer, alleging violations of the ATS, the Connecticut Unfair Trade Practices Act ("CUTPA"), and the Connecticut Products Liability Act ("CPLA") ("the *Adamu* action"). Pfizer moved to dismiss both actions for lack of subject matter jurisdiction and on the basis of *forum non coveniens*.[*] The district court granted the motions and both sets of plaintiffs have appealed.

As explained below, we conclude: (1) that the district court incorrectly determined that the prohibition in customary international law against nonconsensual human medical experimentation cannot be enforced through the ATS; (2) that changed circumstances in Nigeria since the filing of this appeal require re-examination of the appropriate forum, albeit on the basis of a legal analysis different from that employed by the district court; and (3) that the district court incorrectly applied Connecticut's choice of law rules in the *Adamu* action. Consequently, we reverse and remand the cases to the district court for further proceedings.

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[*] [sic.]

## BACKGROUND

### *A. Pfizer's Trovan Test in Nigeria*

On review of a district court's grant of a motion to dismiss, we assume as true the facts alleged in the complaints, construing them in the light most favorable to the appellants. *See Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 115 (2d Cir. 2008). The central events at issue in these cases took place in 1996, during an epidemic of bacterial meningitis in northern Nigeria.[1] The appellants allege that at that time, Pfizer, the world's largest pharmaceutical corporation, sought to gain the approval of the U.S. Food and Drug Administration ("FDA") for the use on children of its new antibiotic, Trovafloxacin Mesylate, marketed as "Trovan." They contend that in April 1996, Pfizer, dispatched three of its American physicians to work with four Nigerian doctors to experiment with Trovan on children who were patients in Nigeria's Infectious Disease Hospital ("IDH") in Kano, Nigeria. Working in concert with Nigerian government officials, the team allegedly recruited two hundred sick children who sought treatment at the IDH and gave half of the children Trovan and the other half Ceftriaxone, an FDA-approved antibiotic the safety and efficacy of which was well-established. Appellants contend that Pfizer knew that Trovan had never previously been

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[1] Bacterial meningitis is a serious and sometimes fatal infection of the fluids surrounding the spinal cord and the brain. Centers for Disease Control and Prevention, Meningococcal Disease: Frequently Asked Questions (May 28, 2008), http://www.cdc.gov/meningitis/bacterial/ faqs.htm.

tested on children in the form being used and that animal tests showed that Trovan had life-threatening side effects, including joint disease, abnormal cartilage growth, liver damage, and a degenerative bone condition. Pfizer purportedly gave the children who were in the Ceftriaxone control group a deliberately low dose in order to misrepresent the effectiveness of Trovan in relation to Ceftriaxone. After approximately two weeks, Pfizer allegedly concluded the experiment and left without administering follow-up care. According to the appellants, the tests caused the deaths of eleven children, five of whom had taken Trovan and six of whom had taken the lowered dose of Ceftriaxone, and left many others blind, deaf, paralyzed, or brain-damaged.

Appellants claim that Pfizer, working in partnership with the Nigerian government, failed to secure the informed consent of either the children or their guardians and specifically failed to disclose or explain the experimental nature of the study or the serious risks involved. Although the treatment protocol required the researchers to offer or read the subjects documents requesting and facilitating their informed consent, this was allegedly not done in either English or the subjects' native language of Hausa. The appellants also contend that Pfizer deviated from its treatment protocol by not alerting the children or their guardians to the side effects of Trovan or other risks of the experiment, not providing them with the option of choosing alternative treatment, and not informing them that the non-governmental organization Médecins Sans Frontières (Doctors Without Borders) was providing a conventional and

effective treatment for bacterial meningitis, free of charge, at the same site.[2]

The appellants allege that, in an effort to rapidly secure FDA approval, Pfizer hastily assembled its test protocol at its research headquarters in Groton, Connecticut, and requested and received permission to proceed from the Nigerian government in March 1996. At the time, Pfizer also claimed to have secured approval from an IDH ethics committee. Appellants allege, however, that the March 1996 approval letter was backdated by Nigerian officials working at the government hospital well after the experiments had taken place and that at the time the letter was purportedly written, the IDH had no ethics committee.[3] Appellants also contend that the

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[2] The appellants further allege that Pfizer failed to follow its protocol in ways that might have mitigated the harm suffered by the children. They contend that Pfizer violated the protocol by administering Trovan orally even though oral absorption is difficult for sick children; conducting no testing prior to administering the drug to determine whether Nigeria's strain of meningitis might be responsive to Trovan; failing to determine that the children in the test had meningitis; and failing to either exclude from the experiment children with liver or joint problems or to test for such problems, even though Trovan was known to exacerbate them. Although Pfizer's protocol called for children receiving Trovan to be switched to Ceftriaxone if they did not respond well to Trovan, Pfizer allegedly did not conduct regular blood tests of the children or switch those who suffered from Trovan-related side effects to Ceftriaxone.

[3] A Nigerian physician who was the principal investigator for the test allegedly admitted that his office created

experiments were condemned by doctors, including one on Pfizer's staff at the time of the Kano trial.

In 1998, the FDA approved Trovan for use on adult patients only. After reports of liver failure in patients who took Trovan, its use in America was eventually restricted to adult emergency care. In 1999, the European Union banned its use.

*B. The Proceedings Below*

In August 2001, the *Abdullahi* plaintiffs sued Pfizer under the ATS, alleging that the experiments violated international law. In September 2002, the district court granted Pfizer's motion to dismiss the *Abdullahi* claims on the ground of *forum non conveniens*, conditioned on Pfizer's consent to litigation in Nigeria. *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118(WHP), 2002 WL 31082956, at *12 (S.D.N.Y. Sept. 17, 2002) ("*Abdullahi I*"). It found that Nigeria was an adequate alternative forum despite plaintiffs' contentions about corruption in the Nigerian court system. *Id.* at *8-10. The district court denied Pfizer's motion to dismiss under Rule 12(b)(6), Fed.R.Civ.P., concluding that the plaintiffs adequately alleged that Pfizer's collusion with the Nigerian government made it a state actor. *Id.* at *5-6.

Meanwhile, another group of children and guardians involved in the Trovan experiment sued in the Federal High Court in Kano, alleging claims under Nigerian law. That case, *Zango v. Pfizer Interna-*

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the back-dated approval letter when the FDA conducted an audit of the experiment in 1997.

*tional, Inc.*, [2001] Suit No. FHC/K/CS/204/2001 (Nigeria), was dismissed in 2003 after plaintiffs voluntarily discontinued the suit following the removal from the bench of the first judge assigned to the action and the second judge's decision to decline jurisdiction for personal reasons. *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118(WHP), 2005 WL 1870811, at *5 (S.D.N.Y. Aug. 9, 2005) ("*Abdullahi III*"). On appeal to this Court from the district court's dismissal in *Abdullahi I*, the *Abdullahi* appellants argued that the dismissal of the *Zango* litigation was a result of rampant corruption, which indicated that the Nigerian judicial system could not provide an adequate alternative forum for their action. Given an inconclusive record regarding the events leading to the dismissal of the *Zango* lawsuit, we vacated the judgment and remanded for further fact-finding on *forum non conveniens*. *See Abdullahi v. Pfizer, Inc.*, 77 Fed.Appx. 48, 53 (2d Cir. 2003) (summary order) ("*Abdullahi II*").

In November 2002, following the dismissal of the *Zango* lawsuit, a number of the *Zango* plaintiffs filed the *Adamu* action. They alleged that in planning the Trovan experiment in Connecticut and in conducting the tests in Nigeria without informed consent, Pfizer violated the CUTPA, the CPLA, and the ATS. Eventually, the *Adamu* action was transferred to the Southern District of New York and consolidated with the *Abdullahi* action. Pfizer then moved to dismiss both cases for failure to state a claim under the ATS and on the basis of *forum non conveniens*. It also moved to dismiss in *Adamu* on the ground that Connecticut choice of law principles require the application of Nigerian law, which bars suit under CUTPA and the CPLA.

The district court granted the motions. *See Abdullahi III*, 2005 WL 1870811; *Adamu v. Pfizer, Inc.*, 399 F.Supp.2d 495 (S.D.N.Y.2005). In *Abdullahi III*, Judge Pauley held that while "[p]laintiffs correctly state that non-consensual medical experimentation violates the law of nations and, therefore, the laws of the United States," they failed to identify a source of international law that "provide[s] a proper predicate for jurisdiction under the ATS." 2005 WL 1870811, at *9, 14. Noting that "a decision to create a private right of action is one better left to legislative judgment in the great majority of cases," he concluded that "[a] cause of action for Pfizer's failure to get any consent, informed or otherwise, before performing medical experiments on the subject children would expand customary international law far beyond that contemplated by the ATS." *Id.* at *13-14 (internal quotation marks omitted).

With regard to the *forum non conveniens* analysis, the district court declined to accept plaintiffs' submissions concerning Pfizer's alleged bribery of Nigerian officials on the ground that they were not based on personal knowledge. *Id.* at *16-17. Finding that the plaintiffs had failed to submit specific evidence that the Nigerian judiciary would be biased against its own citizens in an action against Pfizer, the district court alternatively held that Nigeria was an adequate alternate forum. *Id.* at *16, 18.

Several months later, the district court also granted Pfizer's motion to dismiss the *Adamu* case. *Adamu*, 399 F.Supp.2d 495. It relied on its *Abdullahi III* decision to hold that the plaintiffs could not establish jurisdiction under the ATS. *Id.* at 501. The district court also incorporated the *forum non*

*conveniens* analysis from *Abdullahi III* to find that Nigeria is an adequate forum. *Id.* at 504. Applying the public and private interest factors set forth in *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508-09, 67 S.Ct. 839, 91 L.Ed. 1055 (1947), *superseded by statute on other grounds as recognized in Cowan v. Ford Motor Co.*, 713 F.2d 100, 103 (5th Cir. 1983), the court found that while public interest factors did not support either forum, private interest factors weighed in favor of dismissal. *Adamu*, 399 F.Supp.2d. at 505-06. The district court also dismissed the *Adamu* plaintiffs' Connecticut law claims, concluding that, under Connecticut choice of law principles, the action was governed and barred by Nigerian law. *Id.* at 503.

The *Abdullahi* and *Adamu* plaintiffs appealed. Since then, a tectonic change has altered the relevant political landscape. In May 2007, the state of Kano brought criminal charges and civil claims against Pfizer, seeking over $2 billion in damages and restitution.[4] Around the same time, the federal government of Nigeria sued Pfizer and several of its employees, seeking $7 billion in damages.[5] None of

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[4] Tina Akannam, *Nigeria: Pfizer-Case Adjourned Till May 27*, Vanguard, April 30, 2008, http://allafrica.com/stories/200804300470.html; Joe Stephens, *Pfizer Faces Criminal Charges in Nigeria*, The Washington Post, May 30, 2007, at A10, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/05/29/AR2007052902107.html.

[5] Jonathan Clayton, *Pfizer Under Fire After Drug Trial*, TimesOnline, June 27, 2007, http://business.timesonline.co.uk/tol/business/industry_sectors/health/article1990908.ece; *Nigeria Sues Drugs Giant Pfizer*, BBC

these cases seek compensation for the subjects of the tests, who are the appellants before this Court. Pfizer then notified this Court that in light of these recent developments, which it believed required further consideration by the district court, it would not seek affirmance on the basis of *forum non conveniens.*

## DISCUSSION

The district court dismissed both actions based on its determination that it lacked subject matter jurisdiction because plaintiffs failed to state claims under the ATS. We review dismissal on this ground *de novo*. *Rweyemamu v. Cote*, 520 F.3d 198, 201 (2d Cir. 2008). "To survive dismissal, the plaintiff[s] must provide the grounds upon which [their] claim rests through factual allegations sufficient 'to raise a right to relief above the speculative level.'" *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007)).[6]

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News, June 5, 2007, http://news.bbc.co.uk/2/hi/africa/6719141.stm.

[6] *Twombly* instituted a flexible "plausibility standard," not limited to antitrust cases, which requires the amplification of facts in certain contexts. *Iqbal v. Hasty*, 490 F.3d 143, 155-58 (2d Cir. 2007).

*I. The Alien Tort Statute*

The Alien Tort Statute, 28 U.S.C. § 1350, provides that "[t]he district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." Included in the Judiciary Act of 1789, the statute provided jurisdiction in just two cases during the first 191 years after its enactment. *See Taveras v. Taveraz*, 477 F.3d 767, 771 (6th Cir. 2007). In the last thirty years, however, the ATS has functioned slightly more robustly, conferring jurisdiction over a limited category of claims.

We first extensively examined the ATS in *Filartiga v. Pena-Irala*, 630 F.2d 876 (2d Cir.1980), where we held that conduct violating the law of nations is actionable under the ATS "only where the nations of the world have demonstrated that the wrong is of mutual, and not merely several, concern, by means of express international accords." *Id.* at 888. Following *Filartiga*, we concluded that ATS claims may sometimes be brought against private actors, and not only state officials, *see Kadic v. Karadzic*, 70 F.3d 232, 239 (2d Cir. 1995), when the tortious activities violate norms of "universal concern" that are recognized to extend to the conduct of private parties-for example, slavery, genocide, and war crimes, *id.* at 240. This case involves allegations of both state and individual action. In *Flores v. Southern Peru Copper Corp.*, 414 F.3d 233 (2d Cir. 2003), we clarified that "the law of nations" in the ATS context "refers to the body of law known as customary international law," which "is discerned from myriad decisions made in numerous and varied international and domestic arenas" and "does not stem from any single, defini-

tive, readily-identifiable source." *Id.* at 247-48. These principles are rejected in their entirety by our dissenting colleague. In *Flores*, we concluded that ATS jurisdiction is limited to alleged violations of "those clear and unambiguous rules by which States universally abide, or to which they accede, out of a sense of legal obligation and mutual concern." *Id.* at 252. Applying this standard, we held that the appellants' claim that pollution from mining operations caused lung disease failed to state a violation of customary international law. We reasoned that the "right to life" and the "right to health" were insufficiently definite to constitute binding customary legal norms and that there was insufficient evidence to establish the existence of a narrower norm prohibiting intranational pollution. *Id.* at 254-55.

In 2004, the Supreme Court comprehensively addressed the ATS for the first time in *Sosa v. Alvarez-Machain*, 542 U.S. 692, 124 S.Ct. 2739, 159 L.Ed.2d 718 (2004). Justice Souter, writing for the majority, clarified that the ATS was enacted to create jurisdiction over "a relatively modest set of actions alleging violations of the law of nations" and with "the understanding that the common law would provide a cause of action." *Id.* at 720, 723. The Supreme Court confirmed that federal courts retain a limited power to "adapt [ ] the law of nations to private rights" by recognizing "a narrow class of international norms" to be judicially enforceable through our residual common law discretion to create causes of action. *Id.* at 728-29. It cautioned, however, that courts must exercise this power with restraint and "the understanding that the door [to actionable violations] is still ajar subject to vigilant doorkeeping," permitting only those claims that "rest on a norm of international

character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms [the Supreme Court has] recognized." *Id.* at 725, 729. These 18th-century paradigms consist of offenses against ambassadors, violations of the right to safe passage, and individual actions arising out of piracy. *Id.* at 724. The common theme among these offenses is that they contravened the law of nations, admitted of a judicial remedy, and simultaneously threatened serious consequences in international affairs. *Id.* at 715. Lower courts are required to gauge claims brought under the ATS against the current state of international law, but are permitted to recognize under federal common law only those private claims for violations of customary international law norms that reflect the same degree of "definite content and acceptance among civilized nations" as those reflected in the 18th-century paradigms. *Id.* at 732-33. The Supreme Court in *Sosa* also counseled that "the determination whether a norm is sufficiently definite to support a cause of action should (and, indeed, inevitably must) involve an element of judgment about the practical consequences of making that cause available to litigants" in federal courts. *Id.*

In this way *Sosa* set a "high bar to new private causes of action" alleging violations of customary international law. *Id.* at 727. A federal court can recognize one only if a plaintiff identifies the violation of a norm of customary international law that, as defined by the sources of such law that United States courts "have long, albeit cautiously, recognized," *id.* at 733-34 (referencing *The Paquete Habana*, 175 U.S. 677, 700, 20 S.Ct. 290, 44 L.Ed. 320 (1900)), is sufficiently specific, universal, and obligatory to meet the

standards established by *Sosa*. *See Sosa*, 542 U.S. at 732, 124 S.Ct. 2739 (citing with approval *Tel-Oren v. Libyan Arab Republic*, 726 F.2d 774, 781 (D.C. Cir. 1984) (Edwards, J., concurring), and *In re Estate of Marcos, Human Rights Litig.*, 25 F.3d 1467, 1475 (9th Cir. 1994)). Applying these principles, the Supreme Court held that the plaintiff, a Mexican national who sued a fellow Mexican national under the ATS for allegedly aiding in his illegal abduction by agents of the U.S. Drug Enforcement Agency, had failed to allege the violation of a customary international law norm with the required precision. *Sosa*, 542 U.S. at 738, 124 S.Ct. 2739. The Supreme Court found that the practical consequences of recognizing a general and broad customary international law prohibition of arbitrary detention in a case involving "a single illegal detention of less than a day, followed by the transfer of custody to lawful authorities and a prompt arraignment" would be "breathtaking" and inappropriate. *Id.* at 736, 738, 124 S.Ct. 2739.

Since *Sosa*, this Court has reviewed three judgments dismissing claims under the ATS. In *Khulumani v. Barclay National Bank, Ltd.*, 504 F.3d 254 (2d Cir. 2007) (per curiam), we held that the ATS conferred jurisdiction over multinational corporations that purportedly collaborated with the government of South Africa in maintaining apartheid because they aided and abetted violations of customary international law. *Id.* at 260. In *Vietnam Ass'n for Victims of Agent Orange v. Dow Chemical Co.*, 517 F.3d 104 (2d Cir. 2008), we concluded that the ATS did not support a claim that the defendants violated international law by manufacturing and supplying Agent Orange and other herbicides used by the United States military during the Vietnam War.

*Id.* at 123. We reasoned that the sources of law on which the appellants relied did not define a norm prohibiting the wartime use of Agent Orange that was both universal and sufficiently specific to satisfy the requirements of *Sosa*. *Id.* at 119-23. Similarly, in *Mora v. People of the State of New York*, 524 F.3d 183 (2d Cir. 2008), we held that the norm at issue-one that prohibits the detention of a foreign national without informing him of the requirement of consular notification and access under Article 36(1)(b)(3) of the Vienna Convention on Consular Relations-was insufficiently universal to support a claim under the ATS. *Id.* at 208-09.

Turning now to this appeal, and remaining mindful of our obligation to proceed cautiously and self-consciously in this area, we determine whether the norm alleged (1) is a norm of international character that States universally abide by, or accede to, out of a sense of legal obligation; (2) is defined with a specificity comparable to the 18th-century paradigms discussed in *Sosa*; and (3) is of mutual concern to States.

*A. The Prohibition of Nonconsensual Medical Experimentation on Humans*

Appellants' ATS claims are premised on the existence of a norm of customary international law prohibiting medical experimentation on non-consenting human subjects. To determine whether this prohibition constitutes a universally accepted norm of customary international law, we examine the current state of international law by consulting the sources identified by Article 38 of the Statute of the Interna-

tional Court of Justice ("ICJ Statute"), to which the United States and all members of the United Nations are parties. *Flores*, 414 F.3d at 250; *see, e.g., United States v. Yousef*, 327 F.3d 56, 100-01 (2d Cir. 2003). Article 38 identifies the authorities that provide "competent proof of the content of customary international law." *Flores*, 414 F.3d at 251. These sources consist of:

> (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
>
> (b) international custom, as evidence of a general practice accepted as law;
>
> (c) the general principles of law recognized by civilized nations;
>
> (d) ... judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

Statute of the International Court of Justice, art. 38(1), June 26, 1945, 59 Stat. 1055, 1060, T.S. No. 993 [hereinafter ICJ Statute].

The appellants ground their claims in four sources of international law that categorically forbid medical experimentation on non-consenting human subjects: (1) the Nuremberg Code, which states as its first principle that "[t]he voluntary consent of the human subject is absolutely essential"; (2) the World Medical Association's Declaration of Helsinki, which sets forth ethical principles to guide physicians world-wide and provides that human subjects should be volunteers and grant their informed consent to

participate in research; (3) the guidelines authored by the Council for International Organizations of Medical Services ("CIOMS"), which require "the voluntary informed consent of [a] prospective subject"; and (4) Article 7 of the International Covenant on Civil and Political Rights ("ICCPR"), which provides that "no one shall be subjected without his free consent to medical or scientific experimentation."[7]

The district court found that "non-consensual medical experimentation violates the law of nations and, therefore, the laws of the United States" and cited the Nuremberg Code for support. Abdullahi III, 2005 WL 1870811, at *9. It then noted that "[w]hile federal courts have the authority to imply the existence of a private right of action for violations of *jus cogens* norms of international law, federal courts must consider whether there exist special factors counseling hesitation in the absence of affirma-

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[7] These sources are located respectively at (1) *United States v. Brandt*, 2 Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10, 181 (1949) [hereinafter Nuremberg Trials]; (2) World Med. Ass'n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, art. 20, 22, G.A. Res. (adopted 1964, amended 1975, 1983, 1989, 1996, and 2000), http://www.wma.net/e/policy/pdf/17c.pdf [hereinafter Declaration of Helsinki]; (3) Council for International Organizations of Medical Services [CIOMS], International Ethical Guidelines for Biomedical Research Involving Human Subjects, guideline 4 (3rd ed. 2002), *superseding id.* at guideline 1 (2nd ed. 1993); (4) International Covenant on Civil and Political Rights, art. 7, Dec. 19, 1966, 999 U.N.T.S. 171 [hereinafter ICCPR].

tive action by Congress." *Id.* (internal citations and quotation marks omitted). The district court then separately analyzed the four sources of international law that prohibit nonconsensual medical experimentation on humans and the Universal Declaration of Human Rights. *Id.* at *11-13. It found that with the exception of the Nuremberg Code, these sources contain only aspirational or vague language lacking the specificity required for jurisdiction. *Id.* at *12-13. It also determined that because the United States did not ratify or adopt any of these authorities except the ICCPR, and because even the ICCPR is not self-executing, none of them create binding international legal obligations that are enforceable in federal court. *Id.* at *11-13. Finally, the district court concluded that the plaintiffs failed to provide a proper predicate for ATS jurisdiction because none of the sources independently authorizes a private cause of action and the inference of such a cause of action is a matter best left to Congress. *Id.* at *13-14.[8]

The district court's approach misconstrued both the nature of customary international law and the scope of the inquiry required by *Sosa*. It mistakenly assumed that the question of whether a particular customary international law norm is sufficiently specific, universal, and obligatory to permit the recognition of a cause of action under the ATS is resolved essentially by looking at two things: whether each source of law referencing the norm is binding and

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[8] The district court interchangeably refers to the "lack of jurisdiction" or "lack of subject matter jurisdiction" over plaintiffs' claims, the plaintiffs' failure to state an ATS claim, and their failure to identify a norm that permits the inference of a cause of action.

whether each source expressly authorizes a cause of action to enforce the norm. But *Sosa*, as we have seen, requires a more fulsome and nuanced inquiry. Courts are obligated to examine how the specificity of the norm compares with 18th-century paradigms, whether the norm is accepted in the world community, and whether States universally abide by the norm out of a sense of mutual concern. By eschewing this inquiry, the district court did not engage the fact that norms of customary international law are "discerned from myriad decisions made in numerous and varied international and domestic arenas" and "[do] not stem from any single, definitive, readily-identifiable source." *Flores*, 414 F.3d at 247-48.

The district court also inappropriately narrowed its inquiry in two respects. First, it focused its consideration on whether the norm identified by the plaintiffs is set forth in conventions to which the United States is a party, and if so, whether these treaties are self-executing or executed by federal legislation. While adoption of a self-executing treaty or the execution of a treaty that is not self-executing may provide the best evidence of a particular country's custom or practice of recognizing a norm, *see Flores*, 414 F.3d at 257, the existence of a norm of customary international law is one determined, in part, by reference to the custom or practices of many States, and the broad acceptance of that norm by the international community. Agreements that are not self-executing or that have not been executed by federal legislation, including the ICCPR, are appropriately considered evidence of the current state of customary international law. *See Khulumani*, 504 F.3d at 284 (Katzmann, J., concurring) (noting that "[w]hether a treaty that embodies [a norm of cus-

tomary international law] is self-executing is relevant to, but is not determinative of, [the] question" of whether the norm permits ATS jurisdiction). A formal treaty, moreover, is not the lone primary source of customary international law. The ICJ Statute permits, and *Sosa* encourages, among other things, that courts consider "international custom, as evidence of a general practice accepted as law." ICJ Statute, *supra*, at art. 38(1); *Sosa*, 542 U.S. at 734, 124 S.Ct. 2739 ("[W]here there is no treaty, and no controlling executive or legislative act or judicial decision, resort must be had to the customs and usages of civilized nations.") (quoting *The Paquete Habana*, 175 U.S. at 700, 20 S.Ct. 290).

Second, the district court's consideration of whether each source of law creates binding legal norms failed to credit the fact that even declarations of international norms that are not in and of themselves binding may, with time and in conjunction with state practice, provide evidence that a norm has developed the specificity, universality, and obligatory nature required for ATS jurisdiction. *See Filartiga*, 630 F.2d at 883 ("[A non-binding] Declaration creates an expectation of adherence, and insofar as the expectation is gradually justified by State practice, a declaration may by custom become recognized as laying down rules binding upon the States.") (internal quotation marks omitted). The district court should have considered a greater range of evidence and weighed differently the probative value of the sources on which the appellants relied.

In sum, it was inappropriate for the district court to forego a more extensive examination of whether treaties, international agreements, or State practice

have ripened the prohibition of nonconsensual medical experimentation on human subjects into a customary international law norm that is sufficiently (i) universal and obligatory, (ii) specific and definable, and (iii) of mutual concern, to permit courts to infer a cause of action under the ATS. *See Sosa*, 542 U.S. at 732-35, 124 S.Ct. 2739. We now proceed with such an examination.

*i. Universality*

The appellants must allege the violation of a norm of customary international law to which States universally subscribe. *See Sosa*, 542 U.S. at 732, 124 S.Ct. 2739; *Vietnam Ass'n for Victims of Agent Orange*, 517 F.3d at 117. The prohibition on nonconsensual medical experimentation on human beings meets this standard because, among other reasons, it is specific, focused and accepted by nations around the world without significant exception.

The evolution of the prohibition into a norm of customary international law began with the war crimes trials at Nuremberg. The United States, the Soviet Union, the United Kingdom and France "acting in the interest of all the United Nations," established the International Military Tribunal ("IMT") through entry into the London Agreement of August 8, 1945. M. Cheriff Bassiouni et al., *An Appraisal of Human Experimentation in International Law and Practice: The Need for International Regulation of Human Experimentation*, 72 J.Crim. L. & Criminology 1597, 1640 & n.220 (1981) (internal quotation marks omitted). Annexed to the London Agreement was the London Charter, which served as the IMT's

Constitution. *See* Agreement for the Prosecution and Punishment of the Major War Criminals of the European Axis Powers, with annexed Charter of the International Military Tribunal art. 2, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279. According to the Charter, the IMT had the "power to try and punish persons who, acting in the interests of the European Axis countries, whether as individuals or as members of organizations, committed," among other offenses, war crimes and crimes against humanity. *Id.* at art. 6.

The IMT tried 22 "major" Nazi war criminals leaving "lower-level" war criminals, including "[l]eading physicians ... and leading German industrialists," to be tried in subsequent trials by U.S. military tribunals acting "under the aegis of the IMT." United States Holocaust Memorial Museum, *War Crimes Trials*, Holocaust Encylopedia (2008), http://www.ushmm.org/wlc/article.php?lang=en&ModuleId=10005140. The law that authorized the creation of the U.S. military tribunals, Control Council Law No. 10, was enacted in 1945 by the Allied Control Council, *see id.*, an authority through which the London Agreement signatories exerted joint-control over Germany, *see* Encyclopedia Britannica, *Germany*, Encyclopedia Britannica Online (2009), http://search.eb.com/eb/article-58214. Control Council Law No. 10 stated that its purpose was to "give effect to the terms of ... the London Agreement ... and the [London] Charter," and "to establish a uniform legal basis in Germany for the prosecution of war criminals." Allied Control Council No. 10, preamble, (Dec. 20, 1945), http://avalon.law.yale.edu/imt/imt10.asp. Law No. 10 expressly incorporated the London Agreement, identifying it as an "integral part[ ] of

this Law." *Id.* at art. I. Law No. 10 also authorized military tribunals of the occupying powers to prosecute individuals for the same crimes over which the IMT had jurisdiction, including war crimes and crimes against humanity, *see id.* at arts. II-III, and made military tribunal prosecutions subject to the IMT's right of first refusal, *see id.* at art. III. Consequently, the U.S. military tribunals effectively operated as extensions of the IMT, see Telford Taylor, *Final Report to the Secretary of the Army on the Nuernberg War Crimes Trials Under Control Council Law No. 107*, 107 (1949) [hereinafter Report on Nuernberg War Crimes Trials], available at http://www.loc.gov/rr/frd/Military_Law/pdf/NT_final-report.pdf (explaining that "the trials under Law No. 10 were to be a means of carrying out such 'declarations of criminality' ... as the International Military Tribunal might make" and that "[t]he first [IMT] trial and the 12 following [military tribunal] trials ... form a single sequence based on common principles"), and Control Council Law No. 10 served to implement the commitments undertaken in the London Agreement, *see id.* at 7 (noting that "the two documents supplemented each other" and "[m]ajor criminals not tried under the one could be tried under the other").

In August 1947, Military Tribunal 1, staffed by American judges and prosecutors and conducted under American procedural rules, *see* George J. Annas, *The Nuremberg Code in U.S. Courts: Ethics versus Expediency, in The Nazi Doctors and the Nuremberg Code* 201, 201 (George J. Annas & Michael A. Grodin eds., 1992), promulgated the Nuremberg Code as part of the tribunal's final judgment against fifteen doctors who were found guilty of war crimes and

crimes against humanity for conducting medical experiments without the subjects' consent, *Brandt*, 2 Nuremberg Trials, at 181-82. Among the nonconsensual experiments that the tribunal cited as a basis for their convictions were the testing of drugs for immunization against malaria, epidemic jaundice, typhus, smallpox and cholera. *Id.* at 175-178. Seven of the convicted doctors were sentenced to death and the remaining eight were sentenced to varying terms of imprisonment. *Id.* at 298-300. The tribunal emphasized that

> [i]n every single instance appearing in the record, subjects were used who did not consent to the experiments; indeed, as to some of the experiments, it is not even contended by the defendants that the subjects occupied the status of volunteers.

*Id.* at 183. The judgment concluded that "[m]anifestly human experiments under such conditions are *contrary to the principles of the law of nations* as they result from usages established among civilized peoples, from the laws of humanity, and from the dictates of public conscience." *Id.* (emphasis added and internal quotation marks omitted). The Code created as part of the tribunal's judgment therefore emphasized as its first principle that "[t]he voluntary consent of the human subject is absolutely essential." *Id.* at 181.

The American tribunal's conclusion that action that contravened the Code's first principle constituted a crime against humanity is a lucid indication of the international legal significance of the prohibition on nonconsensual medical experimentation. As Justices of the Supreme Court have recognized,

"[t]he medical trials at Nuremberg in 1947 deeply impressed *upon the world* that experimentation with unknowing human subjects is morally and legally unacceptable." *United States v. Stanley*, 483 U.S. 669, 687, 107 S.Ct. 3054, 97 L.Ed.2d 550 (1987) (Brennan, J., concurring in part and dissenting in part) (emphasis added); *see also id.* at 709-10, 107 S.Ct. 3054 (O'Connor, J., concurring in part and dissenting in part).

Moreover, both the legal principles articulated in the trials' authorizing documents and their application in judgments at Nuremberg occupy a position of special importance in the development of bedrock norms of international law. United States courts examining the Nuremberg judgments have recognized that "[t]he universal and fundamental rights of human beings identified by Nuremberg-rights against genocide, enslavement, and other inhumane acts ...-are the direct ancestors of the universal and fundamental norms recognized as *jus cogens*," from which no derogation is permitted, irrespective of the consent or practice of a given State. *Siderman de Blake v. Republic of Arg.*, 965 F.2d 699, 715 (9th Cir. 1992) (cited in *Sampson v. F.R.G.*, 250 F.3d 1145, 1150 (7th Cir. 2001)). As Telford Taylor, who first served as an assistant to Justice Robert Jackson during his time as Chief Prosecutor for the IMT and then became Chief of Counsel for War Crimes on the Nuremberg trials held under the authority of Control Council Law No. 10, explained, "Nuernberg was based on enduring [legal] principles and not on temporary political expedients, and this fundamental point is apparent from the reaffirmation of the Nuernberg principles in Control Council Law No. 10, and *their application and refinement* in the 12 judg-

ments rendered under that law during the 3-year period, 1947 to 1949." Taylor, *Report on Nuernberg War Crimes Trials*, at 107 (emphasis added).

Consistent with this view, the Code's first principle has endured: "[S]ignificant world opinion has not come to the defense of the nature or manner in which the experiments were conducted in the Nazi concentration camps." Bassiouni et al., *supra*, at 1641. Rather, since Nuremberg, states throughout the world have shown through international accords and domestic law-making that they consider the prohibition on nonconsensual medical experimentation identified at Nuremberg as a norm of customary international law.[9]

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[9] The Fourth Geneva Convention, which entered into force in 1950 and provides protection to civilians in the time of war, elaborates on the application of the norm during armed conflict. Article 32 of the convention prohibits civilian or military agents of the state parties from conducting "medical or scientific experiments not necessitated by the medical treatment of the protected person." Geneva Convention Relative to the Protection of Civilian Persons in Time of War art. 32, Aug. 12, 1949, 6 U.S.T. 3516, 75 U.N.T.S. 287. According to the commentary, "[p]rotected persons must not in any circumstances be used as 'guinea pigs' for medical experiments." *Commentary on the Geneva Conventions of 12 August 1949: IV Geneva Convention Relative to the Protection of Civilian Persons in Time of War* 224 (Oscar Uhler & Henri Coursier eds., 1958). This commentary explains that the prohibition is directly related to the first principle of the Nuremberg Code since "[i]n prohibiting medical experiments on protected persons, the Diplomatic Conference wished to abolish for ever the criminal practices from which thousands of persons suffered in the death camps

In 1955, the draft International Covenants on Human Rights was revised to add a second sentence to its prohibition of torture and cruel, inhuman or degrading treatment or punishment. The addition provided that "[i]n particular, no one shall be subjected without his free consent to medical or scientific experimentation involving risk, where such is not required by his state of physical or mental health." Annotations on the text of the draft International Covenants on Human Rights, at 31, U.N. GAOR, 10th Sess., Annexes, agenda item 28(II), U.N. Doc. A/2929 (July 1, 1955). The clause was later revised to offer the simpler and sweeping prohibition that "no one shall be subjected without his free consent to medical or scientific experimentation." ICCPR, *supra*, at art. 7. This prohibition became part of Article 7 of the ICCPR, which entered into force in 1976, and is legally binding on the more than 160 States-Parties that have ratified the convention without reservation to the provision.[10] By its terms

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of the [second] world war." The practices involved human medical experiments that were objectionable because they were nonconsensual. *See Brandt*, 2 Nuremberg Trials, at 183. The convention is legally-binding on 194 states that have ratified it without reservation to Article 32. *See* International Committee of the Red Cross, Geneva Conventions of 12 August 1949 State Parties, Signatories, Reservations and Declarations, http://www.icrc.org/ihl.nsf/WebSign?ReadForm&id=375&ps=P.

[10] Although certain States-Parties to the ICCPR have made reservations or declarations with respect to Article 7's prohibition of torture and cruel, inhuman or degrading treatment or punishment, we are not aware of any similar qualification by a State-Party to the prohibition of medical or scientific experimentation without the free consent

this prohibition is not limited to state actors; rather, it guarantees individuals the right to be free from non-consensual medical experimentation by any entity-state actors, private actors, or state and private actors behaving in concert.

Its status as a norm that states conceive as legally binding-and therefore part of customary international law-is confirmed by Article 2 of the accord, which requires that "[e]ach State Party ... undertake[] to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant." ICCPR art. 2(1). The international community's recognition in the ICCPR of its obligation to protect humans against nonconsensual medical experimentation, regardless of the source of the action, is powerful evidence of the prohibition's place in customary international law.

It is clear that, as the court mentioned in *Sosa*, the Universal Declaration of Human Rights and the ICCPR themselves could not establish the relevant, applicable rule of international law in that case. *Sosa*, 542 U.S. at 754, 124 S.Ct. 2739. Nonetheless, the ICCPR, when viewed as a reaffirmation of the norm as articulated in the Nuremberg Code, is potent authority for the universal acceptance of the prohibition on nonconsensual medical experimentation. As we discuss below, *see infra* pp. [34a-36a], the fact

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of human subjects. *See* Office of the United Nations High Commissioner for Human Rights, International Covenant on Civil and Political Rights, Declarations and Reservations, http://www2.ohchr.org/english/bodies/ratification/docs/DeclarationsReservationsICCPR.pdf.

that the prohibition on medical experimentation on humans without consent has been consciously embedded by Congress in our law and reaffirmed on numerous occasions by the FDA demonstrates that the United States government views the norm as the source of a binding legal obligation even though the United States has not ratified the ICCPR in full.[11]

In 1964, the World Medical Association adopted the Declaration of Helsinki, which enunciated standards for obtaining informed consent from human subjects. It provided that in clinical research combined with professional care, "[i]f at all possible, consistent with patient psychology, the doctor should obtain the patient's freely given consent after the patient has been given a full explanation," and that non-therapeutic clinical research on a person "cannot be undertaken without his free consent, after he has been fully informed." World Med. Ass'n, *Declaration of Helsinki: Code of Ethics of the World Medical Association*, art. III(3a), G.A. Res. (1964), http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1816102&blobtype=pdf. The Declaration has since been amended five times. The informed consent provision now provides that "subjects must be volunteers and informed participants in the research

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[11] *Khulumani* makes clear that treaties that the United States has neither signed nor ratified-let alone treaties like the ICCPR that the United States has signed but not ratified-may evidence a customary international law norm for ATS purposes where the treaty has been ratified widely and it is clear that the reason for the United States's failure to subscribe to the treaty was unrelated to the particular norm in question. *See Khulumani*, 504 F.3d at 276, 276 n.9 (Katzmann, J., concurring).

project." Declaration of Helsinki, *supra*, at art. 20. The Declaration also requires that "[i]n any research on human beings, each potential subject must be adequately informed of the aims, methods, ... anticipated benefits and potential risks of the study, and the discomfort it may entail" and that researchers "obtain the subject's freely-given informed consent, preferably in writing." *Id.* at art. 22.

Although the Declaration itself is non-binding, since the 1960s, it has spurred States to regulate human experimentation, often by incorporating its informed consent requirement into domestic laws or regulations. *See* Delon Human & Sev S. Fluss, The World Medical Association's Declaration of Helsinki: Historical and Contemporary Perspectives, 8-11 (July 24, 2001) (fifth draft), http://www.wma.net/e/ethicsunit/pdf/draft_historical_contemporary_perspectives.pdf (describing legal and regulatory developments in Australia, Belgium, Brazil, China, Israel, Japan, New Zealand, Norway, Switzerland, and the United States following the Declaration of Helsinki). Currently, the laws and regulations of at least eighty-four countries, including the United States, require the informed consent of human subjects in medical research.[12] That this

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[12] The Department of Health and Human Services has compiled the laws, regulations, and guidelines governing human subjects research in eighty-four countries. *See* Office of Human Research Prot., Dep't of Health & Human Servs., International Compilation of Human Subject Research Protections (2008), http://www.hhs.gov/ohrp/international/HSPCompilation.pdf. It is uncontested that all of the countries identified in this compi-

conduct has been the subject of domestic legislation is not, of course, in and of itself proof of a norm. *See Flores*, 414 F.3d at 249. However, the incorporation of this norm into the laws of this country and this host of others is a powerful indication of the international acceptance of this norm as a binding legal obligation, where, as here, states have shown that the norm is of mutual concern by including it in a variety of international accords.

The history of the norm in United States law demonstrates that it has been firmly embedded for more than 45 years and-except for our dissenting colleague-its validity has never been seriously questioned by any court. Congress mandated patient-subject consent in drug research in 1962. Bassiouni et al., *supra*, at 1624 (citing 21 U.S.C. § 355(i) (1976)). In response, the FDA promulgated its first regulations requiring the informed consent of human subjects. Tellingly, the sources on which our government relied in outlawing non-consensual human medical experimentation were the Nuremberg Code and the Declaration of Helsinki, which suggests the government conceived of these sources' articulation of the norm as a binding legal obligation. Bassiouni et al., *supra*, at 1625-26 (citing 21 C.F.R. § 310.102(h) (1980)).[13] Today, FDA regulations re-

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lation require informed consent to medical experimentation.

[13] The importance of informed consent to medical experimentation was reinforced with the passage of the National Research Act in 1974, which established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *See* National Research Act, Pub. L. 93-348, 88 Stat. 342 (codified

quire informed consent to U.S. investigators' research, whether conducted domestically or in a foreign country, used to support applications for the approval of new drugs. *See* 21 C.F.R. §§ 50.20, 50.23-.25, 50.27, 312.20, 312.120 (2008); 45 C.F.R. §§ 46.111, 46.116-.117 (2008).

The importance that the United States government attributes to this norm is demonstrated by its willingness to use domestic law to coerce compliance with the norm throughout the world. United States law requires that, as a predicate to FDA approval of any new drug, both American and foreign sponsors of drug research involving clinical trials, whether conducted here or abroad, procure informed consent

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as amended in scattered sections of 42 U.S.C.). This body issued the *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* in 1979, which identifies basic ethical principles governing biomedical and behavioral research on human subjects and requires informed consent. Nat'l Comm'n for the Prot. of Human Subjects of Biomedical & Behavioral Research, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, part C(1) (1979), *available at* http://ohsr.od.nih.gov/guidelines/belmont.html#goc. Soon afterwards, the Department of Health, Education and Welfare (later renamed the Department of Health and Human Services) promulgated stricter regulations for ensuring informed consent in research conducted or supported by federal departments or agencies. *See* U.S. Dep't of Health & Human Servs., Guidelines for the Conduct of Research Involving Human Subjects at the National Institutes of Health, 17-18 (5th ed. 2004), http://ohsr.od.nih.gov/ guidelines/GrayBooklet82404.pdf (referencing 45 C.F.R. pt. 46, subpt. A (1981)).

from human subjects. 21 C.F.R. §§ 312.20, 312.120 (2008); *see also* Dep't of Health & Human Servs., Office of Inspector Gen., The Globalization of Clinical Trials 5 (2001), http://www.oig.hhs.gov/oei/reports/oei-01-00-00190.pdf. Sponsors conducting research under an Investigational New Drug Application ("IND") are obligated to adhere to FDA regulations, which require informed consent. 21 C.F.R. § 312.20 (2008); The Globalization of Clinical Trials, *supra*, at 5. Prior to April 2008, sponsors conducting research under non-IND guidelines were obligated to adhere to the ethical principles of the 1989 version of the Declaration of Helsinki or the host country's regulations, whichever offered greater protection to the human subject. 21 C.F.R. § 312.120 (2007); The Globalization of Clinical Trials, *supra*, at 5. The April 2008 revisions to the non-IND guidelines reaf-firmed the informed consent requirement. Human Subject Protection: Foreign Clinical Studies Not Conducted Under an Investigational New Drug Ap-plication, 73 Fed. Reg. 22,800, 22,801, 22,803, 22,804, 22,816 (Apr. 28, 2008) (codified at 21 C.F.R. pt. 312). Foreign clinical studies not conducted under an IND must now comply with the Good Clinical Practice guidelines ("GCP") promulgated by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, 62 Fed. Reg. 25,692 (May 9, 1997), which require informed consent to medical experimentation. 21 C.F.R. § 312.120 (2008).

Additional international law sources support the norm's status as customary international law. The European Union embraced the norm prohibiting nonconsensual medical experimentation through a 2001 Directive passed by the European Parliament and

the Council of the European Union. The Directive accepted the informed consent principles of the 1996 version of the Declaration of Helsinki. Council Directive 2001/20/EC, preamble (2), 2001 O.J. (L 121) 37(EC) [hereinafter 2001 Clinical Trial Directive]. It also required member States to adopt rules protecting individuals incapable of giving informed consent and permitting clinical trials only where "the trial subject or, when the person is not able to give informed consent, his legal representative has given his written consent after being informed of the nature, significance, implications and risks of the clinical trial." *Id.* at art. (1), (2)(d). The Directive further required all member States to implement by 2004 domestic laws, regulations, and administrative provisions to comply with its informed consent requirements. *Id.* at art. 22(1).

Since 1997, thirty-four member States of the Council of Europe have also signed the Convention on Human Rights and Biomedicine, a binding convention and a source of customary international law. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, art. 5, 15-16, *opened for signature* Apr. 4, 1997, E.T.S. No. 164, http://conventions.coe.int/Treaty/en/Treaties/html/164.htm [hereinafter Convention on Human Rights and Biomedicine]; Convention on Human Rights and Biomedicine, Chart of Signatures and Ratifications as of Aug. 8, 2008, http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=8/8/2008&CL=ENG. It provides that an "intervention in the health field may only be carried out after the person concerned has given free and informed consent to it"

and that the informed consent of human subjects is required for their involvement in medical research. Convention on Human Rights and Biomedicine, *supra*, at art. 5.[14] In 2005, the General Conference of the United Nations Educational, Scientific and Cultural Organization (UNESCO) adopted the Universal Declaration on Bioethics and Human Rights, which requires "the prior, free, express and informed consent of the person concerned" for research-oriented treatments. Universal Declaration on Bioethics and Human Rights, UNESCO Gen. Conf. Res., at art. 6, 33rd Sess., 33 C/Resolution 36, (Oct. 19, 2005).

This history illustrates that from its origins with the trial of the Nazi doctors at Nuremburg through its evolution in international conventions, agreements, declarations, and domestic laws and regulations, the norm prohibiting nonconsensual medical experimentation on human subjects has become firmly embedded and has secured universal acceptance in the community of nations. Unlike our dissenting colleague's customary international law analysis, which essentially rests on the mistaken assumption that ratified international treaties are the only valid sources of customary international law for ATS purposes, *see* Dissent at [75a-80a], we reach this conclusion as a result of our review of the multiplicity of sources-including international conventions, whether general or particular, and international cus-

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[14] States-Parties to the Convention on Human Rights and Biomedicine are also required to afford "appropriate judicial protection" to prevent or end infringements of the rights protected by the Convention, including the right to informed consent to medical experimentation. Convention on Human Rights and Biomedicine, *supra*, at art. 23.

tom as identified through international agreements, declarations and a consistent pattern of action by national law-making authorities-that our precedent requires us to examine for the purpose of determining the existence of a norm of customary international law. Our dissenting colleague's reasoning fails to engage the incompatibility of nonconsensual human testing with key sources of customary international law identified in Article 38 of the ICJ's statute, most importantly international custom, as evidence of a general practice accepted as law, as well as the general principles of law recognized by civilized nations. *See supra* pp. [20a-23a].

*ii. Specificity*

*Sosa* requires that we recognize causes of action only to enforce those customary international law norms that are no "less definite [in] content ... than the historical paradigms familiar when [the ATS] was enacted." *Sosa*, 542 U.S. at 732, 124 S.Ct. 2739. The norm prohibiting nonconsensual medical experimentation on human subjects meets this requirement. In *United States v. Smith*, 18 U.S. (5 Wheat) 153, 159-61, 5 L.Ed. 57 (1820), Justice Story found that "whatever may be the diversity of definitions, ... all writers concur, in holding, that robbery or forcible depredations upon the sea ... is piracy." *Id.* at 161. We have little trouble concluding that a norm forbidding nonconsensual human medical experimentation is every bit as concrete-indeed even more so-than the norm prohibiting piracy that Story describes, or interference with the right of safe conducts and the rights of ambassadors, which together are the paradigmatic norms identified in *Sosa*. *Id.*

at 724, 124 S.Ct. 2739. The Nuremberg Code, Article 7 of the ICCPR, the Declaration of Helsinki, the Convention on Human Rights and Biomedicine, the Universal Declaration on Bioethics and Human Rights, the 2001 Clinical Trial Directive, and the domestic laws of at least eighty-four States all uniformly and unmistakably prohibit medical experiments on human beings without their consent, thereby providing concrete content for the norm.[15] The appellants allege that Pfizer knowingly and purposefully conducted such experiments on a large scale. Whatever uncertainty may exist at the margin is irrelevant here because appellants allege a complete failure on the part of Pfizer and the Nigerian government to inform appellants of the existence of the Trovan experiments. These allegations, if true, implicate Pfizer and the Nigerian government in conduct that is at the core of any reasonable iteration of the prohibition against involuntary medical experimentation. While the prohibition in question applies to the

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[15] At the fringe, disagreement exists over certain aspects of informed consent including, for example, the way to best secure consent from illiterate or otherwise vulnerable populations, *see, e.g.*, Daniel W. Fitzgerald et al., *Comprehension During Informed Consent in a Less-Developed Country*, 360 The Lancet 1301, 1301-02 (2002), and whether informed consent is possible in double-blind experiments in which some subjects are given placebos, *see, e.g.*, Timothy S. Jost, *The Globalization of Health Law: The Case of Permissibility of Placebo-Based Research*, 26 Am. J.L. & Med. 175, 183-86 (2000). These debates do not disturb the specificity of the basic norm at issue or the unanimity of world opinion against medical experimentation on human subjects without their consent.

testing of drugs without the consent of human subjects on the scale Pfizer allegedly conducted, we do not suggest that it would extend to instances of routine or isolated failures by medical professionals to obtain informed consent, such as those arising from simple negligence. The allegations in the complaints involve anything but a doctor's routine or erroneous failure to obtain such consent from his patient.

*iii. Mutual Concern*

Customary international law proscribes only transgressions that are of "mutual" concern to States-"those involving States' actions performed ... towards or with regard to the other." *Flores*, 414 F.3d at 249 (differentiating matters of "mutual" concern from those of "several" concern, in which "States are separately and independently interested"). Conduct that States have prohibited through domestic legislation is also actionable under the ATS as a violation of customary international law when nations of the world have demonstrated "by means of express international accords" that the wrong is of mutual concern. *Filartiga*, 630 F.2d at 888. An important, but not exclusive, component of this test is a showing that the conduct in question is "capable of impairing international peace and security." *Flores*, 414 F.3d at 249. Appellants have made both of these showings.

As we have seen, States throughout the world have entered into two express and binding international agreements prohibiting nonconsensual medical experimentation: the ICCPR and the Convention on Human Rights and Biomedicine. The entry of

over 160 States into these agreements and the European Union's passage of the 2001 Clinical Trial Directive demonstrates that States have not only acted independently to outlaw large-scale, nonconsensual drug testing on humans, but they have also acted in concert to do so. In other words, acting out of a sense of mutual concern, "the nations [of the world] have made it their business, both through international accords and unilateral action," to demonstrate their intention to eliminate conduct of the type alleged in the complaints. *Filartiga*, 630 F.2d at 889.

The administration of drug trials without informed consent on the scale alleged in the complaints poses a real threat to international peace and security. Over the last two decades, pharmaceutical companies in industrialized countries have looked to poorer, developing countries as sites for the medical research essential to the development of new drugs. *See* James V. Lavery, *Putting International Research Ethics Guidelines to Work for the Benefit of Developing Countries*, 4 Yale J. Health Pol'y L. & Ethics 319, 320-21 (2004); The Globalization of Clinical Trials, *supra*, at 8.[16] Pharmaceutical companies recognize the potential benefits of drug trials to poor nations and have sought to promote access to medicines and health care in underserved populations through philanthropy and partnership with governments and NGOs. *See, e.g.*, PhRMA, Press Releases: Worldwide Pharmaceutical Industry Launches Global

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[16] In the United States, for example, the number of foreign clinical investigators conducting drug research under an IND increased sixteen-fold in the 1990s. Globalization of Clinical Trials, *supra*, at 6.

Health Progress Initiative to Expand Efforts to Improve Health in Developing Countries (April 16, 2008), http://www.phrma.org/news_room/press_releases/global_health_progress_initiative_launched_to_improve_health_in_developing_countries/ (describing initiative by worldwide pharmaceutical industry to "further access to medicines; build capacity of health workers in developing nations; advocate for global action to address health challenges; and continue R & D to develop new tools to fight diseases that plague the developing world"); PhRMA, Profile2008: Pharmaceutical Industry 42 (2008), http://www.phrma.org/files/2008%20Profile .pdf (describing contributions by American pharmaceutical companies to the promotion of global access to medicines and health care). This trend offers the possibility of enormous health benefits for the world community. Life-saving drugs can potentially be developed more quickly and cheaply, and developing countries may be given access to cutting edge medicines and treatments to assist underresourced and understaffed public health systems, which grapple with life-threatening diseases afflicting their populations.[17]

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[17] These benefits are well acknowledged. *See, e.g.*, Remigius N. Nwabueze, *Ethical Review of Research Involving Human Subjects in Nigeria: Legal and Policy Issues*, 14 Ind. Int'l & Comp. L. Rev. 87, 102 (2003) (recognizing that clinical trials at times provide the only access to innovative and effective health care in developing countries); David Wendler, et al., *The Standard of Care Debate: Can Research in Developing Countries Be Both Ethical and Responsive to those Countries' Health Needs?*, 94 Am. J.

The success of these efforts promises to play a major role in reducing the cross-border spread of contagious diseases, which is a significant threat to international peace and stability. The administration of drug trials without informed consent on the scale alleged in the complaints directly threatens these efforts because such conduct fosters distrust and resistance to international drug trials, cutting edge medical innovation, and critical international public health initiatives in which pharmaceutical companies play a key role. This case itself supplies an exceptionally good illustration of why this is so. The Associated Press reported that the Trovan trials in Kano apparently engendered such distrust in the local population that it was a factor contributing to an eleven month-long, local boycott of a polio vaccination campaign in 2004, which impeded international and national efforts to vaccinate the population

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Pub. Health 923, 923 (2004) (noting dramatic inequalities in health care world-wide and the potential of drug research to better care for the world's poor).

Doctors Without Borders, the WHO, and other international health organizations, for example, have called for increased corporate research interest in developing countries. Sonia Shah, *Globalizing Clinical Research*, The Nation, June 13, 2002, at 3, http://www.thenation.com/doc/20020701/shah. Ruth Faden, a bioethicist at Johns Hopkins, stated, "What we need, if anything, is more health research in the developing world, not less." *Id.* An HIV researcher observed that even when companies test drugs geared for patients in the developed world through trials in developing countries, the testing "brings benefits to the patients. They get special attention and potential therapy." *Id.*

against a polio outbreak with catastrophic results.[18] According to the World Health Organization, polio originating in Nigeria triggered a major international outbreak of the disease between 2003 and 2006, causing it to spread across west, central, and the Horn of Africa and the Middle East, and to reinfect twenty previously polio-free countries.[19]

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[18] Salisu Rabiu, *Pfizer Asks Nigeria Court to Dismiss Case*, The Associated Press, July 4, 2007, http://origin.foxnews.com/printer_friendly_wires/2007Jul04/0,4675,NigeriaPfizer,00.html (reporting that the boycott of the Kano polio vaccination program is believed to have "set back global eradication" of polio and to have "caus[ed] an outbreak that spread the disease across Africa and into the Middle East"). The boycott also impaired the efforts of American pharmaceutical companies to contribute to polio eradication by donating over 130 million doses of polio vaccine to sixteen African countries since 1997. PhRMA, Global Partnerships: Humanitarian Programs of the Pharmaceutical Industry in Developing Nations 4 (2004), http://www.phrma.org/files/Global_Partnerships_2004.pdf.

[19] World Health Organization, *Poliomyelitis in Nigeria and West/Central Africa*, June 18, 2008, http://www.who.int/csr/don/2008_06_18/en/.

Other examples of the link between the cross-border spread of contagious disease and international peace and stability come to mind, such as the outbreak of anti-U.S. riots in South Korea as a result of fear that imported American beef will spread mad cow disease to that country. *See* Choe Sang-Hun, *South Korea Lifts Ban on U.S. Beef*, New York Times, June 26, 2008, http://www.nytimes.com/2008/06/26/world/asia/26korea.html.

The administration of drug trials without informed consent also poses threats to national security by impairing our relations with other countries. Seven of the world's twelve largest pharmaceutical manufacturers-a group that includes Pfizer-are American companies. *Global 500*, Fortune, July 21, 2008, http://money.cnn.com/magazines/fortune/ global500/2008/industries/21/index.html. Consequently, American companies are likely to be sponsors of medical experiments on human subjects abroad.[20] As this case illustrates, the failure to secure consent for human experimentation has the potential to generate substantial anti-American animus and hostility. Unsurprisingly, as noted above, *see supra* p. [35a], our government actively attempts to prevent this practice in foreign countries. For example, federal law requires that data generated from testing on human subjects abroad that is used to seek regulatory approval for a given drug must, at minimum, be the result of testing conducted consistent with the requirements of informed consent. Consequently, the U.S. government denies access to the U.S. market for any new drug unless the drug's research data is generated in a manner consistent with the cus-

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[20] FDA data suggests the industry trend is to use foreign research to support applications for new drug approvals in the United States. Since 1990 there has been an explosion in the number of foreign clinical investigators conducting drug research that sponsors use for this purpose. In 1990, there were 271 foreign investigators conducting research in 28 countries in the FDA database. By 1999, the number had grown to 4,458 investigators working in 79 countries. Globalization of Clinical Trials, *supra*, at i.

tomary international law norm prohibiting drug trials on human subjects without informed consent.

For these reasons, we hold that the appellants have pled facts sufficient to state a cause of action under the ATS for a violation of the norm of customary international law prohibiting medical experimentation on human subjects without their consent. In such an instance, ATS jurisdiction exists over plaintiffs' claims. The district court determined that the norm existed, but concluded that because no single source recognizing the norm was legally binding on the United States and created a private cause of action, it could not infer such a right under the ATS. Presumably, on this basis, it simultaneously held that there was no subject matter jurisdiction over plaintiffs' claims. Under *Sosa*, this approach was not correct. *Sosa* makes clear that the critical inquiry is whether the variety of sources that we are required to consult establishes a customary international law norm that is sufficiently specific, universally accepted, and obligatory for courts to recognize a cause of action to enforce the norm. Nothing in *Sosa* suggests that this inquiry can be halted if some of the sources of international law giving rise to the norm are found not to be binding or not to explicitly authorize a cause of action.

We believe that the issues raised by this appeal regarding customary international law are framed by our analysis and by that of our dissenting colleague. He contends that our analysis is created from "whole cloth." Dissent at [58a]. We believe that his approach to customary international law is unselfconsciously reactionary and static. The approach does not accommodate itself to the normative world that,

by their commitments and conduct over the past fifty years, states-including our own-have shown they believe to exist.

*B. State Action*

A private individual will be held liable under the ATS if he "acted in concert with" the state, i.e., "under color of law." *Kadic*, 70 F.3d at 245. In making this determination, courts look to the standards developed for finding state action in claims brought under 42 U.S.C. § 1983. *Id.* Under § 1983, state action may be found when "there is such a 'close nexus between the State and the challenged action' that seemingly private behavior 'may be fairly treated as that of the State itself.'" *Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 295, 121 S.Ct. 924, 148 L.Ed.2d 807 (2001) (quoting *Jackson v. Metropolitan Edison Co.*, 419 U.S. 345, 351, 95 S.Ct. 449, 42 L.Ed.2d 477 (1974)). That nexus may exist "where a private actor has operated as a willful participant in joint activity with the State or its agents," *Gorman-Bakos v. Cornell Coop. Extension of Schenectady County*, 252 F.3d 545, 551-52 (2d Cir. 2001) (quoting *Loce v. Time Warner Enter-tainment Advance/Newhouse Partnership*, 191 F.3d 256, 266 (2d Cir. 1999)), or "acts together with state officials or with significant state aid," *Kadic*, 70 F.3d at 245. Pfizer meets this test.

The Appellants have alleged that the Nigerian government was involved in all stages of the Kano test and participated in the conduct that violated international law. They allege that the Nigerian government provided a letter of request to the FDA to

authorize the export of Trovan, arranged for Pfizer's accommodations in Kano, and facilitated the nonconsensual testing in Nigeria's IDH in Kano. Despite overcrowding due to concurrent epidemics, the Nigerian government extended the exclusive use of two hospital wards to Pfizer, providing Pfizer with control over scarce public resources and the use of the hospital's staff and facilities to conduct the Kano test, to the exclusion of MSF.

The unlawful conduct is alleged to have occurred in a Nigerian facility with the assistance of the Nigerian government and government officials and/or employees from the IDH and Aminu Kano Teaching Hospital. Pfizer's research team in Kano was comprised of three American physicians, Dr. Abdulhamid Isa Dutse (a physician in the Aminu Kano Teaching Hospital), and three other Nigerian doctors. The American and Nigerian members of Pfizer's team allegedly jointly administered the Kano tEst. Finally, in addition to assisting with the Kano test, Nigerian officials are alleged to have conspired to cover up the violations by silencing Nigerian physicians critical of the test and by back-dating an "approval letter" that the FDA and international protocol required to be provided prior to conducting the medical experiment. In addition to these allegations, the *Adamu* plaintiffs explicitly allege that the Nigerian government "was intimately involved and contributed, aided, assisted and facilitated Pfizer's efforts to conduct the Trovan test," "acted in concert with Pfizer," and, according to a Nigerian physician involved in the Trovan experimentation, appeared to "back[ ]" the testing. At the pleading stage, these contentions meet the state action test because they adequately allege that the

violations occurred as the result of concerted action between Pfizer and the Nigerian government.

*II. Forum Non Conveniens*

As an alternative to dismissal for failure to state a claim under the ATS, the district court dismissed the actions on the ground of *forum non conveniens*. Appellants raised this issue on appeal. Ordinarily, we review a *forum non conveniens* dismissal for abuse of discretion. *Norex Petroleum Ltd. v. Access Indus., Inc.*, 416 F.3d 146, 153 (2d Cir. 2005). Since filing this appeal, however, Pfizer has notified the Court that in light of recent developments, in particular the initiation of proceedings by the federal government of Nigeria and the state of Kano against Pfizer and certain of its employees, it would not seek affirmance of the judgment on the basis of *forum non conveniens*. The appellants agreed and also requested that the issue be remanded. We accede to this request.

Although we are not now called upon definitively to review the district court's application of *forum non conveniens*, in view of the frequency with which this issue has arisen and remained unsettled in this case, we offer additional guidance to assist the parties and the district court. The three-step analysis set forth in *Iragorri v. United Techs. Corp.*, 274 F.3d 65, 71-75 (2d Cir.2001) (en banc), applies. In this litigation, the second step of the analysis, which requires the district court to consider the adequacy of the alternative forum, is pivotal. Dismissal is not appropriate if an adequate and presently available alternative forum does not exist. *Norex*, 416 F.3d at 159. A forum

in which defendants are amenable to service of process and which permits litigation of the dispute is generally adequate. *Id.* at 157. Such a forum may nevertheless be inadequate if it does not permit the reasonably prompt adjudication of a dispute, if the forum is not presently available, or if the forum provides a remedy so clearly unsatisfactory or inadequate that it is tantamount to no remedy at all. *Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 254-55 & n. 22, 102 S.Ct. 252, 70 L.Ed.2d 419 (1981); *USHA (India), Ltd. v. Honeywell Int'l, Inc.*, 421 F.3d 129, 136 (2d Cir. 2005); *Norex*, 416 F.3d at 160.

The defendant bears the burden of establishing that a presently available and adequate alternative forum exists, and that the balance of private and public interest factors tilts heavily in favor of the alternative forum. *USHA (India), Ltd.*, 421 F.3d at 135; *PT United Can Co. v. Crown Cork & Seal Co., Inc.*, 138 F.3d 65, 74 (2d Cir. 1998). Absent a showing of inadequacy by a plaintiff, "considerations of comity preclude a court from adversely judging the quality of a foreign justice system." *PT United Can Co.*, 138 F.3d at 73. Accordingly, while the plaintiff bears the initial burden of producing evidence of corruption, delay or lack of due process in the foreign forum, the defendant bears the ultimate burden of persuasion as to the adequacy of the forum. *See, e.g., Norex*, 416 F.3d at 159-160.

When the district court granted Pfizer's motion, it identified the pivotal issue as whether the plaintiffs produced sufficient evidence to show that Nigeria is an inadequate alternative forum. *Abdullahi III*, 2005 WL 1870811, at *15. Having found that they had not, it concluded that Nigeria was an adequate

forum. *Id.* at *16-18. In so doing, the district court omitted an analysis of whether Pfizer discharged its burden of persuading the court as to the adequacy and present availability of the Nigerian forum and improperly placed on plaintiffs the burden of proving that the alternative forum is inadequate. *Cf. DiRienzo v. Philip Servs. Corp.*, 294 F.3d 21, 30 (2d Cir. 2002) (holding that it is error not "to hold defendants to their burden of proof" of the *Gilbert* factors). On remand, the district court will have an opportunity to reassess this issue, as well as the relationship between Fed.R.Civ.P. 44.1 and the Federal Rules of Evidence.

*III. Choice of Law*

The district court dismissed the Adamu plaintiffs' claims under the Connecticut Unfair Trade Practices Act and the Connecticut Products Liability Act on the ground that Connecticut choice of law principles applied and called for the application of Nigerian law. *Adamu*, 399 F.Supp.2d at 501-03. "We review the district court's choice of law *de novo*." *Fin. One Pub. Co. Ltd. v. Lehman Bros. Special Fin., Inc.*, 414 F.3d 325, 331 (2d Cir.2005).

The district court correctly determined that Connecticut choice-of-law rules applied because it was obligated to apply the state law that would have been applicable if the case had not been transferred from Connecticut to New York. *See Van Dusen v. Barrack*, 376 U.S. 612, 639, 84 S.Ct. 805, 11 L.Ed.2d 945 (1964). Under Connecticut law, *lex loci delicti*, "the doctrine that the substantive rights and obligations arising out of a tort controversy are determined

by the law of the place of injury," typically applies. *O'Connor v. O'Connor*, 201 Conn. 632, 637, 519 A.2d 13 (1986). *Lex loci delicti* would require the application of Nigerian law because the *Adamu* plaintiffs' injuries are alleged to have occurred there. Connecticut, however, has conspicuously retreated from a rigid application of the doctrine. The Connecticut Supreme Court held that *lex loci delicti* does not apply to a tort claim when doing so would undermine expectations of the parties or an important state policy, produce an arbitrary and irrational result, or where "reason and justice" counsel for the application of a different principle. *Id.* at 637, 648, 650, 519 A.2d 13. In such cases, Connecticut courts are required to apply the "most significant relationship" analysis set forth in the Restatement (Second) of Conflict of Laws §§ 6 & 145 (1971) [hereinafter Restatement (Second)]. *O'Connor*, 201 Conn. at 649-50, 519 A.2d 13.

Section 145(1) of the Restatement provides that "[t]he rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6." Restatement (Second) § 145(1). Section 6(2), in turn, provides that where a state is not guided by a statutory directive on choice of law,

> the factors relevant to the choice of the applicable rule of law include
>
> (a) the needs of the interstate and international systems,
>
> (b) the relevant policies of the forum,

> (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
>
> (d) the protection of justified expectations,
>
> (e) the basic policies underlying the particular field of law,
>
> (f) certainty, predictability and uniformity of result, and
>
> (g) ease in the determination and application of the law to be applied.

Restatement (Second) § 6(2). The Connecticut Supreme Court has determined that Section 145(2) provides courts with guidance regarding the evaluation of the policy choices set out in Sections 145(1) and 6(2). *O'Connor*, 201 Conn. at 652, 519 A.2d 13. Section 145(2) assists with the application of the principles of Section 6 to tort cases by calling for consideration of:

> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicil, residence, nationality, place of incorporation and place of business of the parties, and
>
> (d) the place where the relationship, if any, between the parties is centered.

Restatement (Second) § 145(2). These factors are "to be evaluated according to their relative importance with respect to the particular issue." *Id.*

The district court correctly decided to apply Sections 6 and 145 of the Restatement rather than *lex loci delicti*. It applied the factors in Section 145(2) to determine whether Connecticut or Nigeria has the most significant relationship to the conduct at issue, which it identified as "Pfizer's failure to inform the children or their parents about the potential problems with Trovan, and the administration of Trovan and low dosage of Ceftriaxone." *Adamu*, 399 F.Supp.2d at 503 (citations omitted). It reasoned that "the Nigerian contacts to this litigation are stronger than Connecticut's" and noted in particular that both the plaintiffs' injuries and Pfizer's alleged conduct occurred in Nigeria, that the plaintiffs were Nigerian residents, and that "the parties' relationship is centered" in Nigeria. *Id.* It determined that most of the factors of Section 145(2) point toward applying Nigerian law and that the "sole basis" for the applicability of Connecticut law was that "Pfizer performed research and development with respect to Trovan and planned the experiment in Connecticut." *Id.* For these reasons, it concluded that Nigeria's interests were superior and that its law should apply. *Id.*

Although the district court correctly identified some of the pertinent factors, it ultimately erred in its application of the "most significant relationship" test because it did not factor into its Section 145(2) analysis the integral factors set out in Section 6(2). It did not, for example, discuss "the relevant policies of the forum" or "the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue." Restatement (Second) § 6(2)(b)-(c). Nor did it analyze what "justified expectations" existed that could have

prompted Pfizer reasonably to believe that its conduct in Connecticut would not expose it to Connecticut law, or how Pfizer would have been disadvantaged by litigating these claims in Connecticut. *Id.* § 6(2)(d). Finally, the district court did not evaluate its own ability to determine and apply Connecticut, as opposed to Nigerian, law. *Id.* § 6(2)(g). For these reasons, we vacate the dismissal of the state law claims and remand to the district court for further consideration.

## CONCLUSION

For the foregoing reasons, we REVERSE the judgments of the district court and REMAND for further proceedings.

Judge WESLEY dissents in a separate opinion.

WESLEY, Circuit Judge, dissenting:

The majority has undertaken to define a "firmly established" norm of international law, heretofore unrecognized by any American court or treaty obligation, on the basis of materials inadequate for the task. In deviating from our settled case law, the majority *identifies* no norm of customary international law, it creates a new norm out of whole cloth. Because the majority's analysis misconstrues-rather than vindicates-customary international law, I respectfully dissent.

Proceeding with "extraordinary care and restraint," *Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 248 (2d Cir. 2003), this Court has upheld juris-

diction under the Alien Tort Statute, 28 U.S.C. § 1350 ("ATS"), in only a handful of cases alleging violations of the most firmly established international law norms, *see Kadic v. Karadzic*, 70 F.3d 232, 241-43 (2d Cir. 1995) (genocide and war crimes); *Amerada Hess Shipping Corp. v. Argentine Republic*, 830 F.2d 421, 426 (2d Cir. 1987), *rev'd on other grounds*, 488 U.S. 428, 109 S.Ct. 683, 102 L.Ed.2d 818 (1989) (free passage of neutral ship in international waters); *Filartiga v. Pena-Irala*, 630 F.2d 876, 878 (2d Cir. 1980) (state-administered torture). In *Sosa v. Alvarez-Machain*, the Supreme Court identified three such "paradigmatic" norms, namely "violation of safe conducts, infringement of the rights of ambassadors, and piracy." 542 U.S. 692, 724, 124 S.Ct. 2739, 159 L.Ed.2d 718 (2004). Rather than declare that list exhaustive for purposes of the ATS, the Court held that "any claim based on the present-day law of nations [must] rest on a norm of international character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms we have recognized." *Id.* at 725, 124 S.Ct. 2739. Accordingly, we are charged with "vigilant doorkeeping" when reviewing ATS claims to ensure that they rest on "a narrow class of international norms" comparable to the paradigms identified by the Supreme Court. *Id.* at 729, 124 S.Ct. 2739.

The majority identifies three criteria that must be satisfied before a violation of international law can be actionable under the ATS: that the norm is (1) specific and definable, (2) universally adhered to out of a sense of legal obligation, and (3) a matter of mutual concern, namely a matter "involving States' actions performed towards or with regard to the other."

*Flores*, 414 F.3d at 249 (internal quotation and alterations omitted). I agree with the methodology used by the majority to determine whether a norm falls within the jurisdictional grant of the ATS, but I do not agree with their conclusion that a norm against non-consensual medical experimentation on humans by private actors is (1) universal and obligatory or (2) a matter of mutual concern.

The majority relies on eight sources of customary international law to support its determination that a norm against non-consensual medical experimentation on humans by private actors is universal and obligatory. However, this evidence falls far short of the quantum necessary to establish the existence of such a norm: (1) the International Covenant on Civil and Political Rights has been described by the Supreme Court as a "well-known international agreement[ ] that despite [its] moral authority, ha[s] little utility," in defining international obligations, *Sosa*, 542 U.S. at 734, 124 S.Ct. 2739, and moreover, it does not apply to private actors, such as the Defendant in this action; (2) the Council of Europe's Convention on Human Rights and Biomedicine-a regional convention-was not ratified by the most influential nations in the region, such as France, Germany, Italy, the Netherlands, Russia and the United Kingdom, and it was promulgated on April 4, 1997, one year *after* the conduct at issue in this litigation; (3) the UNESCO Universal Declaration of Bioethics and Human Rights of 2005 and (4) the European Parliament Clinical Trial Directive of 2001 both also post-date the relevant time period by several years; (5) the Declaration of Helsinki issued by the World Medical Association, a private entity, and (6) the International Ethical Guidelines for Research Involv-

ing Human Subjects promulgated by the Council for International Organizations for Medical Sciences, another private entity, "express[ ] the sensibilities and the asserted aspirations and demands of some countries or organizations" but are not "statements of universally-recognized legal obligations," *Flores*, 414 F.3d at 262; (7) states' domestic laws, which, unsupported by express international accords, are not "significant or relevant for purposes of customary international law," *id.* at 249; and (8) the so-called Nuremberg Code, a statement of principles that accompanied a criminal verdict, possesses at best "subsidiary" value as a judicial decision, Statute of the International Court of Justice art. 38, June 26, 1945, 59 Stat. 1031, 33 U.N.T.S. 993 ("ICJ Statute"). Taken together, this evidence falls short of charting the existence of a universal and obligatory international norm actionable against non-government actors under the ATS.[1]

In support of its determination that non-consensual medical experimentation by private actors is a matter of mutual concern, the majority reasons that non-consensual medical experiments breed distrust of medical interventions and thereby accelerate the spread of infectious diseases across international borders. It is not enough, however, that tortious conduct could create some sort of international consequence. In order for conduct to be a matter of mutual concern, it must "threaten[ ] serious

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[1] Even if we were to conclude that such a norm applied to state actors and that private entities could be held liable if they act under color of law, Plaintiffs have not pleaded sufficient state involvement to impose liability on Pfizer under that theory. *See* Part III *infra*.

consequences in international affairs." *Sosa*, 542 U.S. at 715, 124 S.Ct. 2739. Such is the case when an ambassador is assaulted, for example, because the assault "impinge[s] upon the sovereignty of the foreign nation and if not adequately redressed could rise to an issue of war." *Id.* Non-consensual medical experimentation by private actors simply does not present the same grave risk of serious consequences in international affairs and is therefore not a matter of mutual concern.

For these reasons, I conclude that non-consensual medical experimentation by private actors, though deplorable, is not actionable under international law and would therefore affirm the district court's dismissal of Plaintiffs' complaints.

## DISCUSSION

### I. *Universal and Legally Obligatory Adherence*

In order for a principle to become a norm of customary international law, states must universally abide by it out of a sense of legal obligation, and not merely aspiration. *See Flores*, 414 F.3d at 248. It might seem obvious, but before one can determine whether a principle is universally followed, one must define the principle in question. Like domestic law, international law is not a monolith-a unitary set of rules applying indiscriminately to all actors that come within its reach. To the contrary, international law consists of rules that govern only states, rules that apply to private parties-individuals and corporations-and other rules that regulate both evenhandedly. *See, e.g.*, Restatement (Third) of Foreign

Relations of the United States § 101 (1987) ("Restatement (Third)"). As a result, the Supreme Court has required courts deciding whether a principle is a customary international law norm to consider "whether international law extends the scope of liability for a violation of a given norm to the perpetrator being sued, if the defendant is a private actor such as a corporation or individual." *Sosa*, 542 U.S. at 732 n.20, 124 S.Ct. 2739; *see also id.* at 760, 124 S.Ct. 2739 (Breyer, J., concurring) ("The norm must extend liability to the type of perpetrator (*e.g.*, a private actor) the plaintiff seeks to sue.").

The majority lists the norm at issue here as the prohibition of "medical experimentation on non-consenting human subjects," Maj. Op. at [20a], and proceeds to analyze that norm without regard to the alleged violator, see *id.* at [20a-50a]. Put another way, the majority's analysis would be no different if Plain-tiffs had sued the Nigerian government, instead of, or in addition to, Pfizer. Such a broad, simplified definition ignores the clear admonitions of the Supreme Court-and conflicts with prior decisions of this Court-that a customary international law norm cannot be divorced from the identity of its violator. The major-ity's analysis omits this critical consideration. As a result, the majority opinion presents only half of the equation. To my mind, the majority should have asked whether customary international law prohibits *private actors* from medical experimentation on non-consenting human subjects. That question must be answered in the negative.

A. *The Majority's Sources of Customary International Law*

In *Flores*, we explained some of the difficulties inherent in determining what offenses violate customary international law:

> Customary international law is discerned from myriad decisions made in numerous and varied international and domestic arenas. Furthermore, the relevant evidence of customary international law is widely dispersed and generally unfamiliar to lawyers and judges. These difficulties are compounded by the fact that customary international law ... does not stem from any single, definitive, readily-identifiable source.

414 F.3d at 247-48. We have consistently looked to the ICJ Statute as the starting point for determining the proper sources of international law. *See, e.g., id.* at 250-51; *United States v. Yousef*, 327 F.3d 56, 100-03 (2d Cir. 2003). That statute lists: (1) "international conventions, whether general or particular, establishing rules expressly recognized by the contesting states"; (2) "international custom, as evidence of general practice accepted as law"; (3) "the general principles of law recognized by civilized nations"; and, in certain circumstances (4) "judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law." ICJ Statute art. 38.

The ability to pick and choose from this seemingly limitless menu of sources presents a real threat of "creative interpretation." *Flores*, 414 F.3d at 248; *see*

*also Amerada Hess*, 830 F.2d at 429 (Kearse, J., dissenting). To mitigate this risk, and to prevent courts from becoming "roving commission[s]," *Flores*, 414 F.3d at 262, we have, in our cases, methodically assessed the weight and relative influence of not only each class of sources listed in the ICJ Statute, but many individual sources within each class. The near-infinite list of international law sources makes adherence to this precedent of paramount importance, for our analysis demonstrates that not every source of international law carries equal weight.

Instead of following and applying our framework, the majority substitutes in its place a compelling narrative. Over the course of only a few pages, the majority employs several sources that it believes demonstrate a customary norm against medical experimentation by non-state entities and weaves them together to reach its conclusion. See Maj. Op. at [21a-41a]. Nowhere does the majority examine these sources in the context required by *Sosa*. The majority does not discuss the weight of these sources, how they collectively demonstrate a customary norm, or how evidence supporting that norm compares with our ATS precedent. Had they done so, I am hopeful that my colleagues would reach the same conclusion that I do-that medical experimentation by private actors, while reprehensible, is not actionable under international law.

### *1. Treaties & Conventions*

In *Flores*, we noted that treaties are the strongest evidence of customary international law because they "create *legal obligations* akin to contractual ob-

ligations on the States parties to them." 414 F.3d at 256. "[W]e look primarily to the formal lawmaking and official actions of States ... as evidence of the established practices of States." *Yousef*, 327 F.3d at 103. But not all treaties are equal. Although "[a]ll treaties that have been ratified by at least two States provide some evidence of the custom and practice of nations ... a treaty will only constitute *sufficient proof* of a norm of customary international law if an overwhelming majority of States have ratified the treaty." *Flores*, 414 F.3d at 256. Moreover, the "evidentiary weight to be afforded to a given treaty varies greatly depending on (i) how many, and which, States have ratified the treaty, and (ii) the degree to which those States actually implement and abide by the principles set forth in the treaty." *Id.* at 256-57. For instance, treaties ratified by the United States are of greater evidentiary value if they are either self-executing or executed through acts of Congress. *See, e.g., id.* at 257; *Khulumani v. Barclay Nat'l Bank Ltd.*, 504 F.3d 254, 284 (2d Cir.2007) (Katzmann, J., concurring).

The majority relies primarily on two treaties.

a. International Covenant on Civil and Political Rights

The International Covenant on Civil and Political Rights, Dec. 9, 1966, S. Exec. Doc. E, 95-2, 999 U.N.T.S. 171, 6 I.L.M. 368 (ratified by the United States June 8, 1992) ("ICCPR") "guarantees a broad spectrum of civil and political rights to individuals within signatory nations." *United States v. Duarte-Acero*, 296 F.3d 1277, 1282 (11th Cir. 2002). One of

those rights-to be free of non-consensual medical or scientific experimentation-is stated in Article 7.

The ICCPR is not appropriate evidence of customary international law for at least two reasons. First, the Supreme Court in *Sosa* explicitly described the ICCPR as a "well-known international agreement[ ] that, despite [its] moral authority, ha[s] *little utility* under the standard set out in this opinion," because the "United States ratified [it] on the express understanding that it was not self-executing and so did not itself create obligations enforceable in the federal courts." 542 U.S. at 734-35, 124 S.Ct. 2739 (emphasis added).

Second, whatever limited weight the ICCPR has with regard to state action, it does nothing to show that a norm prohibiting involuntary medical experimentation applies to non-state entities. In citing its seemingly universal language, the majority overlooks the ICCPR's operative section, which requires that "[e]ach State Party ... undertake[ ] to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant." ICCPR art. 2(1). Thus, despite its broad text, the ICCPR by its own terms, only governs "the relationship between a State and the individuals within the State's territory." *Duarte-Acero*, 296 F.3d at 1283. Because the ICCPR only creates obligations flowing from a state to persons within its territory, a non-state actor cannot be said to have violated it. Thus, the ICCPR was relevant in *Filartiga* (decided before the Supreme Court limited its utility), in the context of state-administered torture of one of its citizens in contravention of one of the rights guaranteed by states in the ICCPR. *See* 630

F.2d at 884. But whatever its evidentiary value had Plaintiffs sued the Nigerian government, the ICCPR clearly has none where the question is whether international law includes a norm actionable against a *private corporation*.

b. Convention on Human Rights and Biomedicine

The second treaty cited by the majority is the Convention on Human Rights and Biomedicine, Apr. 4, 1997, E.T.S. No. 164 (the "Convention"), promulgated by the Council of Europe. See Maj. Op. at [39a-40a]. Articles 5[2] and 16[3] of the Convention re-

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[2] Article 5-General rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks. The person concerned may freely withdraw consent at any time.

[3] Article 16-Protection of persons undergoing research

Research on a person may only be undertaken if all the following conditions are met:

i. there is no alternative of comparable effectiveness to research on humans;

ii. the risks which may be incurred by that person are not disproportionate to the potential benefits of the research;

iii. the research project has been approved by the competent body after independent examination of its scientific merit, including assessment of the impor-

quire that the subject of scientific research give his or her informed consent, which may be withdrawn at any time.

The first problem with the majority's reliance on the Convention is that it is a regional agreement not signed by the most influential states in the region. Membership in the Council of Europe is limited to European states. *See* Statute of the Council of Europe, art. 4, May 5, 1949, E.T.S. No. 1. It is diffi-cult to see how the Convention demonstrates the *universality* of the medical experimentation principle when its signatories are limited to one continent. The majority also notes that the Convention has been signed by thirty-four states, see Maj. Op. at [39a], but overlooks that it has only been ratified by twenty-two, and a treaty only evidences the customs and practices of states that have ratified it. *Flores*, 414 F.3d at 256. Lastly, and perhaps more importantly, the Convention is lacking even as evidence of a European norm, since it has not been ratified by the more influential European states, including France, Germany, Italy, the Netherlands, Russia and the United Kingdom, and a treaty's evidentiary value increases along with the influence in international affairs of the states that have ratified it. *See id.* at

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tance of the aim of the research, and multidisciplinary review of its ethical acceptability;

iv. the persons undergoing research have been informed of their rights and the safeguards prescribed by law for their protection;

v. the necessary consent as provided for under Article 5 has been given expressly, specifically and is documented. Such consent may be freely withdrawn at any time.

257; Convention on Human Rights and Biomedicine, Chart of Signatures and Ratifications as of December 23, 2008, http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=8&DF=12/23/2008&CL=ENG ("Convention Ratifications Chart").

A second, more fundamental problem with the majority's reliance on the Convention is that it was promulgated *after* the conduct at issue here. I know of no authority for an international ex post facto definition of the law of nations by later signed treaties. *Cf. Vietnam Ass'n for Victims of Agent Orange v. Dow Chem. Co.*, 517 F.3d 104, 118 (2d Cir. 2008) ("The United States did not ratify the 1925 Geneva Protocol until 1975. Accordingly, the Protocol cannot be said to have constituted 'a treaty of the United States,' 28 U.S.C. § 1350, during the period relevant to this appeal."). Plaintiffs allege that the Trovan testing occurred in March and April of 1996, but the Convention was not opened for signature until April 4, 1997, and did not bind any state until Slovakia's ratification on January 15, 1998. *See Flores*, 414 F.3d at 256 ("A State only becomes bound by-that is, becomes a party to-a treaty when it ratifies the treaty."); Convention Ratifications Chart. The Convention is without import to this inquiry. Two other post-1996 sources cited by the majority, the 2005 UNESCO Universal Declaration on Bioethics and Human Rights and the 2001 European Parliament Clinical Trial Directive share equal evidentiary irrelevance for the same reason.

*2. Multinational Declarations of Principle*

Plaintiffs and the majority cite several multinational declarations, including the World Medical Association's Declaration of Helsinki and the International Ethical Guidelines for Research Involving Human Subjects promulgated by the Council for International Organizations of Medical Sciences ("CIOMS Guidelines"), as additional evidence that the prohibition against non-consensual medical experimentation applies to non-state actors. In doing so, the majority somehow overlooks our decisions in *Flores* and *Yousef*.

In *Flores*, plaintiffs sought to demonstrate customary international law by reference to multinational declarations. In response, we noted that a declaration, "which may be made by a multinational body, or by one or more States, customarily is a 'mere general statement of policy [that] is unlikely to give rise to ... obligation[s] in any strict sense.'" 414 F.3d at 262 (quoting *1 Oppenheim's International Law* 1189 (Sir Robert Jennings & Sir Arthur Watts, eds., 9th ed. 1996)) (alterations in original). "Such declarations are almost invariably political statements-expressing the sensibilities and the asserted aspirations and demands of some countries or organizations-rather than statements of universally-recognized legal obligations." *Id.* As a result, we concluded that "such declarations *are not proper evidence of customary international law*." *Id.* (emphasis added).

In *Flores*, the declarations we rejected were put forth by international governmental bodies, the Organization of American States and the United Nations Conference on Environment and Development. *Id.* at 263. Here, the two declarations embraced by

the majority were put forward by entirely private organizations-hardly evidence of the state of international law. The Declaration of Helsinki was adopted by the World Medical Association, a group comprised not of member states, but of physicians and private national medical associations. "The World Medical Association (WMA) is an international organization representing physicians .... [and] has always been an independent confederation of free professional associations." *See* The World Medical Association, "About the WMA," http://www.wma.net/e/about/index.htm. The express terms of the Declaration of Helsinki make it abundantly clear that it is hortatory, and not obligatory: "The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles...." *See* World Med. Ass'n, *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects* art. A(1), June 1964. Similarly, CIOMS is "an international non-governmental, non-profit organization." CIOMS, "What is CIOMS?", http://www.cioms.ch/jan2008_what_is_cioms.pdf.

Treating these well-meaning, aspirational, but private, declarations as sources of international law runs counter to our observation in *Yousef* that "no private person-or group of men and women such as comprise the body of international law scholars-*creates* the law." 327 F.3d at 102. This is so for good reason. As we have seen in our ATS jurisprudence, international custom gives rise to legally enforceable obligations. To include the political statements of private organizations in the select and conscribed group of sources capable of creating international law would enfranchise non-democratic, unaccount-

able entities with governmental authority. As a result, these declarations are "not proper evidence of customary international law." *Flores*, 414 F.3d at 262.

The majority focuses its lens on one line in *Filartiga* for the proposition that a "declaration may by custom become recognized as laying down rules binding upon the States." Maj. Op. at [25a] (quoting *Filartiga*, 630 F.2d at 883). In *Filartiga*, we were discussing a *United Nations declaration*, which though not binding, "creates an expectation of adherence" because it "specif[ies] with great precision the obligations of member nations." 630 F.2d at 883. The declarations relied on by the majority were not put forth by a governmental body such as the United Nations but by wholly private organizations, incapable of creating legally binding obligations.

### 3. *State Practice*

The majority also points to the great number of states that, in their respective domestic laws, require informed consent in medical research. That many countries have prohibited private actors from conducting medical experiments or treatments without informed consent is certainly commendable and worthy of praise, but not "significant or relevant for purposes of customary international law."[4] *See Flores*, 414 F.3d at 249. For it is only when states prohibit domestic action as a result of "express international accords" that a wrong becomes a violation of cus-

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[4] Reliance on states' domestic laws also raises questions of mutuality, discussed *infra* at Part II.

tomary international law. *See Filartiga*, 630 F.2d at 888 (quoting *IIT v. Vencap, Ltd.*, 519 F.2d 1001, 1015 (2d Cir. 1975) (Friendly, J.)). No such international accord exists here.

Moreover, "substantive uniformity" among states' domestic laws is only a starting point for demonstrating international custom through individual state practice, which should also reflect a "procedural" consensus among states on how that behavior should be prosecuted-criminally and civilly. *See Sosa*, 542 U.S. at 761-62, 124 S.Ct. 2739 (Breyer, J, concurring). As Justice Breyer noted in his *Sosa* concurrence, the states of the world have reached both substantive and procedural agreement with respect to only a handful of certain international law norms made actionable against non-state entities. *See id.*; Part I(B) *infra*. Non-consensual medical testing is not among them.

### 4. *The Nuremberg Code*

The majority centers its analysis around the Nuremberg Code, but, in the process, critically misstates its genesis and status in international law. *See* Maj. Op. at [26a-32a]. Because the Code is a *sui generis* source of international law, its context is vital to understanding what it is-and what it is not.

The Nuremberg trials are unquestionably one of this country's greatest and most enduring contributions to the field of international law. As early as 1943, the Allied powers contemplated bringing Nazi war criminals to justice after the conclusion of the Second World War. At the October 1943 Moscow Conference, the United States, United Kingdom and

Soviet Union issued a joint "Statement on Atrocities," warning that:

> At the time of granting of any armistice to any government which may be set up in Germany, those German officers and men and members of the Nazi party who have been responsible for or have taken a consenting part in the above atrocities, massacres and executions will be sent back to the countries in which their abominable deeds were done in order that they may be judged and punished according to the laws of these liberated countries and of free governments which will be erected therein.

Moscow Declaration Statement of Atrocities, Oct. 30, 1943, 9 U.S. Dept of State Bull. 310 (signed by President Roosevelt, Prime Minister Churchill and Premier Stalin). The statement added that German criminals "whose offenses have no particular geographical localization ... will be punished by joint decision of the government of the Allies." *Id.*

Following victory in Europe and the surrender of Germany, the Allies executed the London Charter on August 8, 1945, establishing an International Military Tribunal to try the "major war criminals," London Charter, Agreement for the Prosecution and Punishment of the Major War Criminals of the European Axis, art. 3, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279, and leaving the door open for other war criminals to be tried in any other "national or occupation court" that might be established, *id.* art. 6. Alongside the London Charter, the Allies promulgated the Charter of the International Military Tribunal and formed a four-member tribunal with one

member appointed by each of the Allies, with jurisdiction over "the major war criminals" accused of committing three crimes: crimes against peace,[5] war crimes,[6] and crimes against humanity.[7] Charter of the International Military Tribunal, arts. 2, 6, Aug. 8, 1945, 59 Stat. 1544, 82 U.N.T.S. 279. It was the International Military Tribunal that conducted the celebrated trial that resulted in the convictions of 19 of 22 defendants, including high-ranking Nazi officials Hermann Goering, Rudolf Hess, and Karl Doe-

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[5] "Crimes Against Peace" were defined as "planning, preparation, initiation or waging of a war of aggression, or a war in violation of international treaties, agreements or assurances, or participation in a common plan or conspiracy for the accomplishment of any of the foregoing." Charter of the International Military Tribunal art. 6(a).

[6] "War Crimes" were defined as "violations of the laws or customs of war. Such violations shall include, but not be limited to, murder, ill-treatment or deportation to slave labor or for any other purpose of civilian population of or in occupied territory, murder or ill-treatment of prisoners of war or persons on the seas, killing of hostages, plunder of public or private property, wanton destruction of cities, towns or villages, or devastation not justified by military necessity." Charter of the International Military Tribunal art. 6(b).

[7] "Crimes Against Humanity" were defined as "murder, extermination, enslavement, deportation, and other inhumane acts committed against any civilian population, before or during the war; or persecutions on political, racial or religious grounds in execution of or in connection with any crime within the jurisdiction of the Tribunal, whether or not in violation of the domestic law of the country where perpetrated." Charter of the International Military Tribunal art. 6(c).

nitz. *See generally* Robert H. Jackson, Final Report to the President on the Nuremberg Trials (Oct. 7, 1946). But the Nuremberg Code was adopted by a different tribunal in a different trial.

Four months after the London Charter established the International Military Tribunal, the Allied Control Council, the joint allied entity that governed post-war Germany, enacted Control Council Law No. 10, which authorized each of the occupying Allies, within its own "Zone of Occupation," to arrest and prosecute "persons within such Zone suspected of having committed a crime,"[8] subject to a right of first refusal by the International Military Tribunal. Allied Control Council Law No. 10 art. III, §§ 1, 3 (Dec. 20, 1945), in *1 Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10*, XVIII (William S. Hein & Co., Inc. 1997) (1949), *available at* http://www.loc.gov/rr/frd/Military_law/pdf/NT_war-criminals_Vol-I.pdf ("*1 Trials of War Criminals*").

The first of the American trials arising under Control Council Law No.10 was the "Medical Case" against German doctors. On October 25, 1946, the American Office of Military Government for Germany enacted General Order 68, constituting Military Tribunal 1, comprised of three American military judges and one alternate judge. *Id.* at 5.

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[8] In addition to the three crimes listed in the Charter of the International War Tribunal, Control Council Law No. 10 added a fourth-"Membership in categories of a criminal group or organization declared criminal by the International Military Tribunal." Control Council Law No. 10 art. II, § (d).

That same day, Brigadier General Telford Taylor, Chief of Counsel for War Crimes, signed an indictment in *United States v. Karl Brandt, et al.* charging 23 defendants with war crimes, crimes against humanity, and conspiracy, and charging 10 of the defendants with membership in the "SS," an organization declared criminal by the International Military Tribunal. *Id.* at 8-18. These charges were premised, primarily, on the defendants' forced medical experiments, which constituted war crimes when performed on prisoners of war, and crimes against humanity when conducted on Nazi concentration camp prisoners.

At the conclusion of the Medical Case, 16 of the 23 defendants were convicted of one or more of the charges, and seven were ultimately sentenced to death. Along with their verdict, the military judges enumerated ten principles that came to be known as the Nuremberg Code, the first of which states that in medical experiments, the "voluntary consent of the human subject is absolutely essential." 2 *Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10*, 181 (William S. Hein & Co., Inc. 1997) (1949), *available at* http://www.loc.gov/rr/frd/Military_law/pdf/NT_war-criminals_Vol-II.pdf ("2 *Trials of War Criminals*").

My colleagues contend that the Code flowed naturally from the principles of law espoused in the London Charter. They are quite right, of course, that Control Council Law No. 10 was modeled after the London Charter and the American and International military tribunals shared largely the same general international law and procedural frameworks. The London Charter identified and defined certain inter-

national law offenses-Crimes Against Humanity, Crimes Against Peace, and War Crimes-while each of the twelve trials before the American military tribunal concerned a unique and horrific context for the commission of those crimes, ranging from medical experimentation on prisoners to the use of slave labor. For example, the definitions of Crimes Against Humanity and War Crimes under which the Nazi doctors were tried in the Medical Case were virtually identical to those of the London Charter. However, the majority overlooks the fact that the Nuremberg Code dealt not with these general principles of law, but instead with the very specific issue of permissible medical experimentation. The ethical principles espoused in the Code had no forebears in either the London Charter or the judgment of the International Military Tribunal. They were developed exclusively in the Medical Case.

I recite this history not to suggest that the Nuremberg Code is not an extraordinary or groundbreaking document, but rather to demonstrate the difficulty inherent in measuring its evidentiary weight, as it does not fit neatly into any of the categories this Court has identified for sources of international law. For one thing, the Code was developed by the United States military and announced by an American military court. *See United States v. Stanley*, 483 U.S. 669, 687, 107 S.Ct. 3054, 97 L.Ed.2d 550 (1987) (Brennan, J., dissenting). Certainly, the Code is not a treaty and did not immediately bind any state. Under the framework of the ICJ Statute-and, accordingly, this Court-because it was part of a criminal verdict, its closest analogue is a judicial decision, but judicial decisions are only "subsidiary," rather than primary, sources of cus-

tomary international law. *See* ICJ Statute art. 38; Maj. Op. at [16a-20a]. I agree with my colleagues that the Code has had significant import-influence that continues to this day. The Code surely has evidentiary value in our inquiry, but there is nothing to indicate that the Code establishes a norm of international law prohibiting non-consensual medical experimentation or treatment by private actors, or compensates for the virtually non-existent evidentiary value of the other sources cited by the majority.

Conscious of our obligation to measure the weight of the sources of international law in the aggregate, what is the sum of the sources that serve as the cornerstone of the majority's conclusion? The ICCPR, characterized by the Supreme Court as being of "little utility," *Sosa*, 542 U.S. at 734, 124 S.Ct. 2739, which, in any event, does not apply to private actors; a pair of private organizations' declarations that our Circuit precedent tells us "are not proper evidence of customary international law," *Flores*, 414 F.3d at 262; one regional convention and two multi-national declarations that post-date the critical time period and are thus completely irrelevant; states' domestic laws untethered to any international agreement that we are told is not "significant or relevant for purposes of customary international law," *id.* at 249, 414 F.3d 233; and the Nuremberg Code, a document whose evidentiary value is unclear.

Simply put, the evidence here does not compare with the sources put forward in the few cases where we have held a principle to be a norm of customary international law. Exercising "extraordinary care and restraint," *see id.* at 248, we have only upheld ATS jurisdiction in cases where the evidence of cus-

tomary international law was entirely overwhelming.[9] In *Filartiga*, we were persuaded by the fact that the "international consensus surrounding torture has found expression in *numerous* international treaties and accords." 630 F.2d at 883 (emphasis added). There, the State Department-"the political branch with principal responsibility for conducting the international relations of the United States," *Flores*, 414 F.3d at 262-had expressly announced that the prohibition against torture had ripened into a norm of customary international law.[10] *Filartiga*, 630 F.2d at 884. In *Kadic*, we observed that genocide was included in section 404 of the Restatement and that the Convention on the Prevention and Punish-

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[9] The majority purports to include our recent decision in *Khulumani v. Barclay National Bank Ltd.*, 504 F.3d 254 (2d Cir. 2007) (per curiam) in this select group, stating that it "held that the ATS conferred jurisdiction over multinational corporations that purportedly collaborated with the government of South Africa in maintaining apartheid because they aided and abetted violations of customary international law." Maj. Op. at [19a]. To the contrary, *Khulumani* did not confer jurisdiction and did not make any determination on whether plaintiffs had stated a violation of international law. It merely held that the district court erred in concluding that the ATS did not convey jurisdiction for "aiding and abetting violations of customary international law," and remanded for consideration of whether plaintiffs had alleged such a violation that the defendants could have been liable for aiding and abetting. *See Khulumani*, 504 F.3d at 260.

[10] Indeed, the Supreme Court later declared that in ATS actions, "federal courts should give serious weight to the Executive Branch's view of the case's impact on foreign policy." *Sosa*, 542 U.S. at 733 n.21, 124 S.Ct. 2739.

ment of the Crime of Genocide had been ratified by more than 120 nations, including the United States, 70 F.3d at 240-42, while international criminalization of war crimes was established by four Geneva Conventions, ratified by more than 180 nations, including the United States, *id.* at 242-43. In *Amerada Hess*, it was similarly obvious that Argentina's Falkland War attack on an American ship violated one of the oldest customary international law norms. 830 F.2d at 423-24. We cited a variety of international accords establishing the right of a neutral ship to free passage. *Id.* at 424. After tracing the norm to Blackstone, we concluded that it was "beyond controversy that attacking a neutral ship in international waters ... violates international law." *Id.*

In those cases, the evidence of international acceptance of each norm with respect to each defendant was "clear and unambiguous." *Flores*, 414 F.3d at 252. In each case, the nations of the world gathered to ratify in universal numbers treaties that specifically prohibited genocide, war crimes, torture, and attacks on neutral ships-not in generalized human rights agreements but in accords with those discrete norms as their exclusive subjects.

My colleagues contend that I look only to the presence (or, in this case, the absence) of a globally ratified treaty as the exclusive source of an international law norm. Far from it-we have held that customary international law "does not stem from any single, definitive, readily-identifiable source." *Id.* at 248. However, the great weight of ATS jurisdiction must rest upon a foundation sturdy enough to support it. Just as it would be error to stubbornly require one source of sufficient strength to bear that

burden on its own, the majority is equally mistaken in its attempt to employ a series of extraordinarily weak sources to secure a purported norm of customary international law. Our case law makes clear that even when viewed collectively, these sources are incapable of carrying the weight placed upon them by my colleagues.

B. *Restatement § 404*

Nor does Plaintiffs' purported norm resemble the select few norms for which international law extends liability to private actors. Although the law of nations in general does not "confine[ ] its reach to state action," *see Kadic*, 70 F.3d at 239, courts must still consider whether the specific norm at issue does. In *Kadic*, we noted that the Restatement (Third) of Foreign Relations Law of the United States differentiates between "those violations that are actionable when committed by a state[11] and a more limited cat-

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[11] Section 702 provides:

> A state violates international law if, as a matter of state policy, it practices, encourages, or condones
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> (a) genocide,
>
> (b) slavery or slave trade,
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> (c) the murder or causing the disappearance of individuals,
>
> (d) torture or other cruel, inhuman, or degrading treatment or punishment,
>
> (e) prolonged arbitrary detention,
>
> (f) systematic racial discrimination, or

egory of violations" that apply with equal force to private actors. *Id.* at 240 (citing Restatement (Third) §§ 404, 702). Section 404 of the Restatement authorizes universal criminal jurisdiction over non-state entities "for certain offenses recognized by the community of nations as of universal concern, such as piracy, slave trade, attacks on or hijacking of aircraft, genocide, war crimes, and perhaps certain acts of terrorism, even where [no other basis of jurisdiction] is present."[12] Universal jurisdiction, not to be confused with universal acceptance of a norm for ATS purposes, "permits a State to prosecute an offender of any nationality for an offense committed outside of that State and without contacts to that State." *Yousef*, 327 F.3d at 103.

The plaintiffs in *Kadic* alleged that Radovan Karadzic, the "president" of the self-proclaimed republic of Srpska violated several international law norms, notably bans on genocide, war crimes and torture. 70 F.3d at 236-37. Treating Karadzic as a non-state actor, we reviewed not only the Restate-

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(g) a consistent pattern of gross violations of internationally recognized human rights.

[12] The Court explained its application of a criminal law provision to a civil statute by noting that a comment to section 404 "permits states to establish appropriate civil remedies such as the tort actions authorized by the [ATS]." *Kadic*, 70 F.3d at 240 (citation omitted). More specifically, "jurisdiction on the basis of universal interests has been exercised in the form of criminal law, but international law does not preclude the application of non-criminal law on this basis, for example, by providing a remedy in tort or restitution for victims of piracy." Restatement (Third) § 404 cmt. b.

ment, but a host of relevant international accords, leading us to conclude that by their own terms, the norms prohibiting genocide and war crimes applied to private individuals, while torture and summary execution "are proscribed by international law only when committed by state officials or under color of law." *Id.* at 241-43. We added that the " 'color of law' jurisprudence of 42 U.S.C. § 1983 is a relevant guide to whether a defendant has engaged in official action for purposes of jurisdiction under the [ATS]." *Id.* at 245.

Five years later, we again determined whether an international law norm applied only to state actors. *See Bigio v. Coca-Cola Co.*, 239 F.3d 440 (2d Cir. 2000). Building on *Kadic*, we held that ATS jurisdiction over a non-governmental entity requires the violation of a norm "listed as an 'act of universal concern' in § 404 or ... sufficiently similar to [those] acts for us to treat them as though they were incorporated into § 404 by analogy," or conduct committed under color of law. *Id.* at 448. In affirming the district court's dismissal, we determined that the act at issue-discriminatory expropriation of property-is much more like the acts listed in section 702 than those in section 404, and that the complaint did not allege that Coca-Cola acted in concert with Egyptian state officials. *Id.* at 447-49. However, unlike in *Kadic*, we saw no need to look beyond the Restatement to any sources of international law in order to conclude that the norm did not apply to non-state entities. *Compare id.* at 448, *with Kadic*, 70 F.3d at 241-43. It is equally clear that section 404 of the Restatement does not reveal a norm of customary international law prohibiting non-consensual medical experimentation by *private actors*.

To reiterate, section 404 lists only five specific acts for which universal criminal jurisdiction over private actors exists: piracy, genocide, slave trade, war crimes, and attacks on aircrafts. *See also Vietnam Ass'n for Victims of Agent Orange*, 517 F.3d at 116 (describing these five as comprising "the list of principles that may be said to have ripened into universally accepted norms of international law" (internal quotation marks omitted)). If anything, this Court has been even more stringent, holding that in spite of the Restatement, federal courts could not try an alleged airline bomber under customary international law principles of universal jurisdiction.[13] *See Yousef*, 327 F.3d at 103-08. Regardless, there is no dispute that none of the five acts in section 404 encompasses non-consensual medical experimentation. Instead, Plaintiffs argue that it is "sufficiently similar" to those acts to support its application to a pri-

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[13] Yousef was charged with placing a bomb aboard a Philippine Airlines jet flying from the Philippines to Japan. 327 F.3d at 81, 88. After holding that customary international law could not support universal juris-diction, we observed that "treaties may diverge broadly from customary international law," *id.* at 108, and upheld jurisdiction under 18 U.S.C. § 32, the statute implementing the "extradite or prosecute" provision of the Montreal Convention for the Suppression of Unlawful Acts Against the Safety of Civil Aviation (Sabotage) art. 7, Sept. 23, 1971, 24 U.S.T. 565, 974 U.N.T.S. 177 ("The Contracting State in the territory of which the alleged offender is found shall, if it does not extradite him, be obliged, without exception whatsoever and whether or not the offence was committed in its territory, to submit the case to its competent authorities for the purpose of prosecution."), *id.* at 108-10.

vate corporation.[14] *See Bigio*, 239 F.3d at 448. This Court has never had occasion to consider what types of acts are "sufficiently similar" to the section 404 acts except to conclude in *Bigio* that discriminatory expropriation was not among them. *Id.* For similar reasons, neither is non-consensual medical experimentation.

Universal jurisdiction originated with prosecutions of piracy more than 500 years ago. *See Yousef*, 327 F.3d at 104; *United States v. Lei Shi*, 525 F.3d 709, 723 (9th Cir. 2008). As we explained in *Yousef*, piracy is universally punishable not because it is uniquely heinous but "because of the threat that piracy poses to orderly transport and commerce between nations and because the crime occurs statelessly on the high seas." 327 F.3d at 104. By 1822, it was beyond "doubt ... that vessels and property in the possession of pirates may be lawfully seized on the high seas by [any] person, and brought in for adjudication." *United States v. the La Jeune Eugenie*, 26 F. Cas. 832, 843 (C.C.D. Mass. 1822) (No. 15,551); *see also United States v. Smith*, 18 U.S. 153, 5 Wheat. 153, 163, 5 L.Ed. 57 (1820) (Story, J.) (discussing the bases for universal jurisdiction over piracy).

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[14] I note the tension between our holding in *Bigio* that acts can, at least in theory, be incorporated into § 404 by analogy for ATS purposes, *see* 239 F.3d at 448, and our statement in *Yousef* that the "strictly limited set of crimes subject to universal jurisdiction cannot be expanded by drawing an analogy between some new crime ... and universal jurisdiction's traditional subjects" for purposes of exercising criminal jurisdiction, *see* 327 F.3d at 103-04.

Private actors trading slaves (as opposed to those engaging in slavery in general) are subject to universal criminal jurisdiction because the early treaties that formed the basis for customary international law considered the slave trade akin to piracy. For example, the 1841 Treaty of London provided that:

> Their Majesties the Emperor of Austria, the King of Hungary and Bohemia, the King of Prussia, and the Emperor of all the Russians, engage to prohibit all trade in slaves, either by their respective subjects, or under their respective flags, or by means of capital belonging to their respective subjects; and *to declare such traffic piracy*. Their Majesties further declare that any vessel which may attempt to carry on the Slave Trade, shall, by that fact alone, lose all right to the protection of their flag.

Treaty for the Suppression of the African Slave Trade art. I, Dec. 20, 1841, 92 Consol. T.S. 437 (emphasis added), *reprinted in* M. Cherif Bassiouni & Edward M. Wise, *Aut Dedere Aut Judicare: The Duty to Extradite or Prosecute in International Law* 132-33 (1995); *see also* Kenneth C. Randall, *Universal Jurisdiction Under International Law*, 66 Tex. L. Rev. 785, 798 (1988) ("Currently, states can recognize universal jurisdiction over slave trading by ... customary law."). Although we declined to hold in *Yousef* that the principle had ripened into a customary norm, attacks on airliners logically fit into this class because, like the high seas, airspace is stateless and extraterritorial.

After World War II, universal criminal jurisdiction was extended to private actors-including many

of the Nazi defendants prosecuted under Control Council Law No. 10-accused of crimes against humanity such as war crimes and genocide because, like piracy, "'there is ... a lack of any adequate judicial system operating on the spot where the crime takes place-in the case of piracy it is because the acts are on the high seas and in the case of war crimes because of a chaotic condition or irresponsible leadership in time of war.'" *Yousef*, 327 F.3d at 105 (quoting Willard B. Cowles, *Universality of Jurisdiction Over War Crimes*, 33 Cal. L. Rev. 177, 194 (1945)); *see also Flores*, 414 F.3d at 244 n.18 ("Customary international law rules proscribing crimes against humanity, including genocide, and war crimes, have been enforceable against individuals since World War II.").

In *Yousef*, we concluded that these acts share two common traits: they "(1) are universally condemned by the community of nations, and (2) by their nature occur either outside of a State or where there is no State capable of punishing, or competent to punish, the crime." 327 F.3d at 105.

Non-consensual medical experimentation is not "sufficiently similar" to these crimes to warrant its incorporation into section 404 by analogy. Plaintiffs acknowledge that the acts listed in section 404 share "a particular quality of crossing international boundaries," a quality that they argue that medical experimentation shares "because of the universal uses of medical research and the common practice of physicians to travel to crisis areas to deliver humanitarian aid." But the mere crossing of an international border does not give rise to universal jurisdiction over non-state actors. We made this clear in *Yousef*,

where we rejected universal jurisdiction over an individual accused of bombing of an aircraft leaving the Philippines for Japan. 327 F.3d at 98, 103. As we held, universal criminal jurisdiction over private actors is only appropriate for acts which, "by their nature," are beyond state sovereignty. *Id.* at 105. Here, Pfizer's alleged actions occurred exclusively within Nigeria, and medical experimentation is not a crime which, by its nature, is incapable of state punishment. Plaintiffs' argument to the contrary is belied by the state and federal civil and criminal actions pending against Pfizer in Nigeria. *See* Maj. Op. at [12a-15a].

As in *Bigio*, medical experimentation more closely resembles the acts for which only state actors may be held responsible. Plaintiffs compare medical experimentation with slavery. Yet, under the Restatement, while anyone may be prosecuted for engaging in the slave trade, slavery itself is only actionable against state actors. *See* Restatement (Third) § 702(b) ("A state violates international law if, as a matter of state policy, it practices, encourages, or condones ... slavery ..."). Medical experimentation resembles slavery in its grievous exploitation of unconsenting and unwilling subjects; it also resembles torture in its infliction of horrific physical and emotional pain. However, both the Restatement and this Court have recognized that the norm against torture reaches only state actors. *See Kadic*, 70 F.3d at 243-44; Restatement (Third) § 702(d); *see also* Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment art. 1, Dec. 10, 1984, S. Treaty Doc. No. 100-20, 1465 U.N.T.S. 85 ("CAT") (defining torture as being "inflicted by or at the instigation of or with the consent or acquiescence

of a public official or other person acting in an official capacity.").[15]

One of the fundamental attributes of sovereignty is a state's authority to exercise criminal jurisdiction over persons accused of committing crimes within its territory. The crimes listed in section 404 are not the extraordinary exceptions because they are singularly reprehensible or deserving of condemnation. Few would argue that piracy, for which private actors may be prosecuted universally but which requires neither an act of violence nor the infliction of physical injury,[16] is more heinous than torture or slavery, practices made actionable only against state entities. Rather, by definition, these crimes occur in locations where, or during times when, sovereignty, and *a fortiori* criminal jurisdiction, are incapable of being exercised. Because medical experimentation is entirely *intra* national and fully subject to domestic criminal jurisdiction, it is not "sufficiently similar" to those acts listed in section 404, and cannot be incorporated by analogy as to reach private, non-state actors.

The defendants in the Medical Case were not charged with conducting non-consensual medical

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[15] It should be noted that while universal criminal jurisdiction under the CAT does exist for torturers, those torturers must, by definition, be state actors. *See* CAT arts. 4, 7, 8.

[16] *See, e.g.*, United Nations Convention on the Law of the Sea part VII, art. 101, Dec. 10, 1982, S. Treaty Doc. No. 103-39, 1833 U.N.T.S. 3 (stating that piracy may consist of "any illegal acts of violence or detention, or any act of depredation....")

tests per se. Rather, those tests, when conducted on prisoners of war and members of a discrete civilian population imprisoned in concentration camps, constituted "war crimes" and "crimes against humanity," offenses for which customary international law has imposed individual responsibility. *See Flores*, 414 F.3d at 244 n.18. Unlike the Defendant in this action, the Nazi doctors convicted by the American military tribunal were not private actors. Each convicted defendant held a position of authority in either the medical services or the military of the Third Reich.[17] *See* 1 Trials of War Criminals 29. Moreover, the atrocities for which they were convicted victimized state prisoners in state-administered concentration camps, according to the Indictment, "for the benefit of the German Armed Forces." Id. at 11-14. It is difficult to imagine a more egregious example of the violation of a customary international law norm or a more appropriate case for ATS jurisdiction.

The majority today authorizes the exercise of ATS jurisdiction over an entirely private corporation for violating a previously unrecognized norm of international law. In doing so, my colleagues accept proof far weaker than in any other case where this Court

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[17] All but three of the 23 defendants were doctors. *1 Trials of War Criminals* 29. The three that were not were colonels or senior colonels in the Nazi SS. *1 Trials of War Criminals* 8, 29. Of the 20 doctors, all but one "held positions in the medical services of the Third Reich." 1 *Trials of War Criminals* 29. The lone exception, Adolf Pokorny, a specialist in skin and venereal diseases, was acquitted of all charges. *1 Trials of War Criminals* 10; *2 Trials of War Criminals* 292-94.

has identified a norm of customary international law, and, apparently, overlook the fact that this purported norm in no way resembles those few norms enforceable against private entities. When tasked by the Supreme Court with "vigilant doorkeeping" to ensure that the list of actionable international norms remains "narrow," *Sosa*, 542 U.S. at 729, 124 S.Ct. 2739, we must be no less demanding than we have been in the past. Under that standard, the evidence put forward by Plaintiffs does not establish a norm of customary international law actionable against private actors. I believe that the majority's decision departs from our settled case law and lowers considerably our previously high bar for ATS jurisdiction.

## II. *Mutuality*

There are many principles on which most states of the world community agree. Most find support and enforcement in the richly diverse legal systems in place around the globe. But universal acceptance as a normative principle is not enough to gain entrance into the "law of nations." The norm must not only be universal, it must touch on matters that are "of mutual, and not merely several, concern." *Filartiga*, 630 F.2d at 888. Matters are of mutual concern when they "affect[ ] the relationship between states or between an individual and a foreign state, and [are] used by those states for their common good and/or dealings inter se." *IIT*, 519 F.2d at 1015. On the other hand, matters of several concern are those "in which States are separately and independently interested." *Flores*, 414 F.3d at 249. For example, as we noted in *Flores*, "murder of one private party by

another, universally proscribed by the domestic law of all countries ... is not actionable under the [ATS] as a violation of customary international law because 'the nations of the world' have not demonstrated that this wrong is of mutual, and not merely several, concern." *Id.* (quotation marks omitted). The majority concludes that non-consensual medical experimentation by one private party on another is a matter of mutual concern. I disagree.

We have consistently held that the best evidence that states consider a matter to be of mutual concern is the fact that they have agreed to be bound "by means of express international accords." *Filartiga*, 630 F.2d at 888; *see Flores*, 414 F.3d at 249; *Khulumani*, 504 F.3d at 274 n.7 (Katzmann, J., concurring). The majority points to the ICCPR, the Convention on Human Rights and Biomedicine, and the 2001 Clinical Trial Directive as evidence that "States throughout the world have entered into ... express and binding international agreements prohibiting nonconsensual medical experimentation." *See* Maj. Op. at [43a]. But those agreements fail to demonstrate mutuality for the same reason they fail to demonstrate universality-the ICCPR does not address acts by non-state actors and the other two were not in force at the time of the alleged misconduct. Whatever international consensus has been reached as to non-consensual medical experimentation by private actors has not yet "found expression in numerous treaties and accords," *cf. Filartiga*, 630 F.2d at 883. The majority cites no worldwide, multicontinental, universally applicable "Convention Against Medical Experimentation," because, at the moment, none exists. That fact alone distinguishes this case from *Filartiga*, *Amerada Hess*, and *Kadic*.

In the absence of a binding global treaty, the majority seeks to demonstrate mutuality of concern by describing the downstream effects of non-consensual medical experimentation. In essence, the majority contends that non-consensual medical experiments feed distrust among their victims, which, in turn, engenders a general reluctance to seek future medical attention or vaccination, which, in turn, helps accelerate the spread of infectious diseases across international borders. *See* Maj. Op. at [44a-49a]. Indeed, I would concede that the majority may be quite right. But a smaller, more interdependent world community has not been employed by the Supreme Court (or any other court to my knowledge) to convert claims such as those presented here into violations of the law of nations. In fact, the majority's theory would be no different when evaluating the medical malpractice of Pfizer's research physicians or the strict products liability for its allegedly defective drug, but malpractice and products liability are among the quintessential subjects of domestic law.

It is not enough that a wrong could create international ramifications; in order for it to be a matter of mutual concern, it must "threaten[ ] serious consequences in international affairs." *Sosa*, 542 U.S. at 715, 124 S.Ct. 2739. The Supreme Court listed three historical mutual wrongs as guideposts to frame this inquiry: infringement of the rights of ambassadors, the violation of safe conducts and piracy. *Id.* at 715, 720, 124 S.Ct. 2739. An assault against an ambassador "impinged upon the sovereignty of the foreign nation and if not adequately redressed could rise to an issue of war." *Id.* at 715, 124 S.Ct. 2739. The 18th century safe-conduct document was the historical equivalent of the modern passport, "which entitles a

bearer with a valid visa to safe passage to, within, and out of a foreign land pursuant to a treaty or an agreement negotiated by his or her sovereign and the host sovereign." *Taveras v. Taveraz*, 477 F.3d 767, 773 (6th Cir. 2007) (quoting Thomas H. Lee, *The Safe-Conduct Theory of the Alien Tort Statute*, 106 Colum. L. Rev. 830, 874 (2006)). Thus, "the purpose of the doctrine of safe conducts under the law of nations is to protect the safety and security of the person and property of the journeying alien bearing the safe conduct privilege (and consequently to preserve commercial and diplomatic relationships between the alien's host and home countries)." *Id.* at 773-74. This is still true today-a passport issued by the United States contains an official request from the Secretary of State to an authority of another sovereign state: "The Secretary of State of the United States of America hereby requests all whom it may concern to permit the citizen/national of the United States named herein to pass without delay or hindrance and in case of need to give all lawful aid and protection." Breaches of customary international law impair the normal expectations that nations have in dealing with other nations. They must threaten serious consequences in international affairs because the norms were, and still are, the foundation for states' formal relationships with one another.

Piracy does not fit squarely with the other two *Sosa* historical paradigms, but the threat to international affairs posed by piracy needs no detailed exegesis. Suffice it to say that one of the young Republic's first military tests was its campaign against the Barbary Pirates, *see, e.g.*, Act For the Protection of the Commerce and Seamen of the United States Against the Tripolitan Cruisers, ch. IV, § 2,

2 Stat. 129, 130 (1802) (authorizing President Jefferson to instruct the armed forces to "seize and make prize of all vessels, goods and effects, belonging to the Bey of Tripoli ... and also to cause to be done all such other acts of precaution or hostility as the state of war will justify, and may, in his opinion, require."), and piracy continues to threaten serious consequences in international affairs today, *see* S.C. Res. 1851, ¶ 2, U.N. Doc. S/RES/1851 (Dec. 16, 2008) (calling upon states "to take part actively in the fight against piracy and armed robbery at sea off the coast of Somalia").

We have accepted no lesser showing in our case law. The threat posed by genocide is so great that states are empowered to request "the competent organs of the United Nations to take such action under the Charter of the United Nations as they consider appropriate for the prevention and suppression of acts of genocide." Convention on the Prevention and Punishment of the Crime of Genocide art. 8, Dec. 9, 1948, 102 Stat. 3045, 78 U.N.T.S. 277. The Geneva Conventions collectively establish, and obligate contracting parties to follow, the laws of war-almost by definition a matter of international affairs. *See Kadic*, 70 F.3d at 242-43. On the other hand, because international law does not define torture to include acts by private entities, torturous conduct by non-state actors-while criminalized domestically-is not a matter of mutual concern. *Id.* at 243-44.

Demonstrating that a wrong is a matter of mutual concern must necessarily be difficult. The Supreme Court has only opened the door for ATS jurisdiction over a "narrow set of violations of the law of nations, admitting of a judicial remedy and at the

same time threatening serious consequences in international affairs." *Sosa*, 542 U.S. at 715, 124 S.Ct. 2739. The nations of the world have not yet demonstrated that non-consensual medical experimentation by non-state actors "is of mutual, and not merely several, concern, by means of express international accords." *Filartiga*, 630 F.2d at 888. Nor does it threaten serious consequences in international affairs in the same manner or to the same extent as the historical paradigms listed by the Supreme Court or their modern counterparts identified by this Court. Without either showing, I cannot agree with the majority that non-consensual medical experimentation *by private actors* is a matter of mutual concern.

## III. *State Action*

The fact that medical experimentation by private actors is not a subject of customary international law does not end the inquiry. If international law supports state liability but not private liability, a private actor may still be liable if he or she "acted under color of law." In that regard, we are told to employ our 42 U.S.C. § 1983 jurisprudence in the inquiry. See Bigio, 239 F.3d at 448; Kadic, 70 F.3d at 245. As an initial matter, this requires that the law of nations includes a norm actionable against states, which, in the instant case, is far from certain. But even assuming, for argument's sake, that international law prohibits states from conducting non-consensual medical tests, Plaintiffs have not demonstrated that Pfizer acted under the color of law.

This issue requires a bit of procedural context. In 2002, Pfizer moved to dismiss Plaintiffs' complaint in *Abdullahi* on the grounds that (1) Plaintiffs had not alleged that Pfizer was a state actor, and (2) the alternate ground of forum non conveniens. *See Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118, 2002 WL 31082956, at *12 (S.D.N.Y. Sept. 17, 2002). Judge Pauley granted the forum non conveniens motion, but denied the state action motion, concluding that Plaintiffs "sufficiently allege[d] that the former Nigerian government and Pfizer were joint participants in the Trovan treatment." *Id.* at *6. Plaintiffs appealed the district court's dismissal, and Pfizer cross-appealed from the court's denial of its motion to dismiss on state action. *See Abdullahi v. Pfizer, Inc.*, 77 Fed.Appx. 48 (2d Cir. 2003). On appeal, we vacated the district court's judgment of dismissal, and did not reach Pfizer's cross-appeal, noting that our intervening decision in *Flores* might have some application on remand. *Id.* at 53. Back before Judge Pauley, Pfizer filed a new motion to dismiss, arguing that Plaintiffs failed to state a claim under the substantially different ATS landscape which now included the Supreme Court's decision in Sosa and our decision in Flores. *See Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118, 2005 WL 1870811, at *3 (S.D.N.Y. Aug. 9, 2005). Both of these decisions made clear that the identity of the defendant is a critical component of whether a principle is a norm of customary international law. Without addressing or affirming its previous conclusion finding sufficient allegations of state action, the district court granted Pfizer's motion to dismiss, holding that medical experimentation was not actionable under the law of nations. *Id.* at *18. On appeal to this Court, both parties addressed the

issue of state action in their briefs. The majority concludes that Plaintiffs' allegations of state action were sufficient to defeat a motion to dismiss. *See* Maj. Op. at [50a-52a]. I cannot agree.

In their twin complaints, which total 628 paragraphs, Plaintiffs make only four allegations concerning the role of the Nigerian government in the Trovan experiments: (1) in order for the FDA to authorize the export of Trovan, "Pfizer obtained the required letter of request from the Nigerian government"; (2) the government "arrang[ed] for Pfizer's accommodation in Kano"; (3) the government acted "to silence Nigerian physicians critical of [Pfizer's] test"; and (4) the government "assign[ed] Nigerian physicians to assist in the project."[18] Elsewhere in their complaints, Plaintiffs note in conclusory fashion that a Nigerian doctor did not publicly object to the Trovan study because it "seemed to have the backing of the Nigerian government."

In their brief to this Court, Plaintiffs seek to bolster their complaints by describing the role of "Nigerian government doctors" at the allegedly government-owned hospital that hosted the study. However, the portions of the complaints that they cite do not support their contentions. Nowhere in their complaints did Plaintiffs allege that the hospital was, in fact, government owned or administered, nor did they allege that the four Nigerian doctors working with Pfizer were employed by the govern-

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[18] Plaintiffs also initially allege that the government backdated a letter of approval for the test, but then allege that the letter was in fact created by a "Nigerian physician whom Pfizer says was its principal investigator."

ment, and our review of a decision to grant a motion to dismiss "is limited to the facts as asserted within the four corners of the complaint" and any attached documents. *McCarthy v. Dun & Bradstreet Corp.*, 482 F.3d 184, 191 (2d Cir. 2007).

These bare allegations are plainly insufficient to survive a motion to dismiss for lack of state action. The Supreme Court's case law on state action is hardly a model of clarity, but certain principles are well-settled. As a threshold matter, the conduct alleged attributable to the state must be defined with the requisite specificity. "When analyzing allegations of state action, we begin 'by identifying the specific conduct of which the plaintiff complains,'" *Tancredi v. Metro. Life Ins. Co.*, 316 F.3d 308, 312 (2d Cir.2003) (quoting *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 51, 119 S.Ct. 977, 143 L.Ed.2d 130 (1999)), and in most cases, a finding of state action "must be premised upon the fact that the State is *responsible*" for that specific conduct, *Horvath v. Westport Library Ass'n*, 362 F.3d 147, 154 (2d Cir. 2004) (internal quotation omitted). Determining state action in these cases "requires tracing the activity to its source to see if that source fairly can be said to be the state." *Leshko v. Servis*, 423 F.3d 337, 340 (3d Cir. 2005); *see also Hadges v. Yonkers Racing Corp.*, 918 F.2d 1079, 1082-83 (2d Cir. 1990). As we recently stated, when confronted with a motion to dismiss, it "is not enough ... for a plaintiff to plead state involvement in *some activity* of the institution alleged to have inflicted injury upon a plaintiff; rather, the plaintiff must allege that the state was involved with the *activity that caused the injury* giving rise to the action." *Sybalski v. Indep. Group Home*

*Living Program, Inc.*, 546 F.3d 255, 257-58 (2d Cir. 2008) (internal quotations omitted).

Here, that activity was not, as the majority apparently concludes, conducting the Trovan trials in general, but rather administering the drug without informed consent. Although Plaintiffs allege that the Nigerian government requested the import of Trovan and arranged for Pfizer's accommodations and some medical staff in Kano, they do not allege that the government or any government employee played any role in either administering Trovan without consent or deciding to do so in the first instance. The Supreme Court has described "the typical case raising a state-action issue" as one in which "a private party has taken the decisive step that caused the harm to the plaintiff, and the question is whether the State was sufficiently involved to treat that decisive conduct as state action." *NCAA v. Tarkanian*, 488 U.S. 179, 192, 109 S.Ct. 454, 102 L.Ed.2d 469 (1988). Plaintiffs have not alleged any facts that would indicate that the answer here is "yes."

Plaintiffs' complaints are more noteworthy for what they do not allege than what they do. They have not suggested that Pfizer was exercising any delegated state authority, *cf. West v. Atkins*, 487 U.S. 42, 108 S.Ct. 2250, 101 L.Ed.2d 40 (1988), or that the Nigerian government "knowingly accept[ed] the benefits derived from [the unlawful] behavior," *Tarkanian*, 488 U.S. at 192, 109 S.Ct. 454. Plaintiffs have not alleged that Pfizer *conspired* with government officials to deprive the subjects of their rights, *cf. Fries v. Barnes*, 618 F.2d 988, 991 (2d Cir. 1980), nor have they alleged that the Nigerian government exercised any coercive power over Pfizer, *cf. Brent-*

*wood Acad. v. Tenn. Secondary Sch. Athletic Ass'n*, 531 U.S. 288, 296, 121 S.Ct. 924, 148 L.Ed.2d 807 (2001). In fact, Plaintiffs did not allege that any Nigerian government officials even knew about the non-consensual tests, because if Nigerian government doctors were somehow involved in the study, Plaintiffs did not specify what role, if any, they played.

The case of *Beanal v. Freeport-McMoRan, Inc.*, 969 F.Supp. 362 (E.D. La. 1997), *aff'd* 197 F.3d 161 (5th Cir. 1999), is instructive. In *Beanal*, plaintiffs seeking to recover under the ATS sought to establish state action on the basis of the Indonesian military's involvement in allegedly actionable conduct. The court rejected that argument, holding that plaintiffs had not "alleged whether the military personnel helped enforce Freeport's policies or merely observed ... the violative conduct." *Id.* at 378. Broad conclusory statements of state involvement are not sufficient to establish state action; "there must be some allegation indicating that the troops jointly cooperated in the conduct, jointly participated in the conduct, influenced the conduct or played an integral part in the deprivation of human rights." *Id.* at 379. The same is true here.[19] Plaintiffs' allegations are inadequate.

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[19] The case relied upon by the district court is entirely distinguishable. *See Nat'l Coal. Gov't of the Union of Burma v. Unocal, Inc.*, 176 F.R.D. 329 (C.D. Cal. 1997). There, plaintiffs survived a motion to dismiss by alleging that Unocal and the Burmese government were joint venturers and partners in a pipeline, with the Burmese government retaliating against protesters with military action and forced labor imposed by the Burmese military

Even without alleging that the State "coerced or even encouraged" the act complained of, Plaintiffs can still survive a motion to dismiss if "the relevant facts show pervasive entwinement to the point of largely overlapping identity between the State and the entity that the plaintiff contends is a state actor." *Horvath*, 362 F.3d at 154 (quotation omitted). This line of cases revolves around the relationship between the state and the actor, as opposed to the specific act. Showing "overlapping identity" is highly uncommon, and most often arises where a private actor is performing one of the few functions traditionally and exclusively reserved to the state or is controlled by a state entity. State assistance by itself is insufficient-the relevant question is whether the *decisionmakers* were ostensibly state actors. We answered that question in the affirmative in Horvath, where half of the putatively private defendant's trustees were state appointees. *Id.* at 153. But the assistance alleged by Plaintiffs-helping to procure a ward in a hospital and arranging for the assistance of a handful of doctors-is not enough to clear this hurdle. Using government property, government staff, and even government funds does not make a private entity a state actor when its decisions are made independently of the state. *See Yeo v. Town of Lexington*, 131 F.3d 241, 254 (1st Cir. 1997) (en banc).

Plaintiffs' generalized allegations (unsupported by factual allegations) that the government acted to silence critics of the test are no more helpful. They

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with Unocal's knowledge. *Id.* at 348. There, as opposed to here, the state committed the unlawful acts.

do not allege who these government officials were, how they acted to silence critics, or when in the sequence of events this conduct occurred. Such a "merely conclusory allegation that a private entity acted in concert with a state actor does not suffice to state a § 1983 claim against the private entity." *Ciambriello v. County of Nassau*, 292 F.3d 307, 324 (2d Cir. 2002).

At most, Plaintiffs' complaints alleged that the Nigerian government acquiesced to or approved the Trovan program in general without knowing its disturbing details. That it approved the program is hardly surprising-in the midst of a widespread epidemic, the Nigerian government likely welcomed help from every entity offering it, but "[m]ere approval of or acquiescence in the initiatives of a private party is not sufficient to justify holding the State responsible for those initiatives." *Blum v. Yaretsky*, 457 U.S. 991, 1004-05, 102 S.Ct. 2777, 73 L.Ed.2d 534 (1982). Plaintiffs have not demonstrated that Pfizer acted "under the color of law" such that it can be held liable for the Nigerian government's alleged violation of the "law of nations."

* * * * * * * * * * * * * *

Plaintiffs' allegations paint a vivid picture of the unspeakable pain and suffering of dozens of innocent children. The issue on this appeal, however, is not whether Pfizer's alleged conduct was "wrong," or even whether it is legally actionable, but whether it falls within both the "narrow class" of international norms for which ATS jurisdiction exists, and the even smaller subset of those norms actionable

against non-state actors. Our Court and the Supreme Court have made it pellucidly clear that ATS jurisdiction must be reserved only for acts that the nations of the world collectively determine interfere with their formal relations with one another-including those rare acts by private individuals that are so serious as to threaten the very fabric of peaceful international affairs. I cannot agree with my colleagues that Pfizer's alleged conduct poses the same threat or is so universally and internationally proscribed as to fit within that narrow class.

I respectfully dissent.

## APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE
SECOND CIRCUIT

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At a stated Term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, in the City of New York, on the 9th day of April, two thousand and nine,

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Rabi Abdullahi, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatau Abdullahi, Salisu Abullahi, individually and as the natural guardian and personal representative of the estate of his son Abulliahi {Manufi} Salisu, Alasan Abdullahi, individually and as the natural guardian and personal representative of the estate of his daughter Firdausi Abdullahi, Ali Hashimu, individually and as the natural guardian and personal representative of the estate of his daughter Suleiman, Muhammadu Inuwa, individually and as the natural guardian and personal representative of the estate of his son Abdullahi M. Inuwa, Magaji Alh Laden, individually and as the natural guardian and personal representative of the estate of his son Kabiru Isyaku, Alhaji Mustapha, individually and as the natural guardian and personal representative of the estate of his daughter Asma'u Mustapha, Suleiman Umar, individually and as the natural guardian and personal representative of the estate of his son Buhari Suleiman, Zainab Ab-

du, a minor, by her mother and natural guardian, Haja Abdullahi, Haji Abdullahi, individually, Firdausi Abdullahi, a minor, by her father and natural guardian Abdullahi Madawaki, Abdullahi Madawaki, individually, Sani Abdullahi, a minor, by his father and natural guardian, Sani Abdullahi, Abdullahi Ado, a minor, by his mother and natural guardian, Aisha Ado, Aisha Ado, individually, Abdumajid Ali, a minor, by his father and natural guardian, Alhaji Yusuf Ali, Nura Muhammad Ali, a minor, by his father and natural guardian, Muhammad Ali, Muhammad Ali, individually, Umar Badamasi, a minor, by his father and natural guardian, malam Badamasi Zubairu, Malam Badamasi Zubairu, individually, Muhammadu Fatahu Danladi, a minor, by his father and natural guardian, Alhaji Danladi Ibrahim, Alhaji Danaldi Ibrahim, individually, Dalha Hamza, a minor, by his father and natural guardian malam Hamza Gwammaja, Malam Gwammaja, individually, Tasiu Haruna, a minor, by his guardian Mukhtar Saleh, Mukhtar Saleh, individually, Muhyiddeen Haasan, a minor, by his father and natural guardian, Tijjani Hassan, Tijjani Hassan, individually, Kawu Adamu Ibrahim, a minor, by his father and natural guardian, Malam Abamus Ibrahim Adamu, Alhaji Ibrahim Haruna, individually, Mallam Idris, individually, Yusuf Idris, a minor, by his father and naturall guardian, Idris Umar, Idris Umar, individually, Hafsat Isa, a minor, by her father and natural guardian,, Isa Muhammed Isa, Isa Muhammed Isa, individually, Taju Isa, a minor, by her father and natural guardian, Malam Isa Usman, Malam Isa Usman, individually, Hadiza Isyaku, a minor, by her father and natural guardian, Isyaki Shuaibu, Isyaku Shuaibu, individually, Za-

hra'u Jafaru, a minor, by her father and antural guardian, Jafru Baba, Jafaru Baba, individually, Anas Mohammed, a minor, by his father and natural guardian, Malam Mohammed, Malam Mohammed, individually, Nafisatu Muhammed, a minor, by her mother and natural guardian, Yahawasu Muhammed, Yahawasu Muhammed, individually, Muhsinu Tijjani, a minor, by his father and natural guardian, Tijjani Hassan, Alhaji Yusuf Ali, Maryam Idris, a minor, by her father and natural guardian, Malam Idris, Ajudu Ismaila Adamu, individually and as parent and natural guardian of Yahaya Ismaica, minor, Malam Mohammed, individually and as parent and natural guardian of Bashir Mohammed, minor, Malam Yusab Ya'u Amale, individually and as parent and natural guardian of Suyudi Yusals Yu' a, minor, Malasm Haruna Adamu, individually and as parent and natural guardian of Mohammed Tasi'u Haruna, minor, Zangon Kwajalawa, individually and as parent and natural guardian of Nuruddim Dauda, minor, Malam Dahauru Ya'y, individually and as parent and natural guardian of Rabi Dahuru, minor and as parent and natural guardian of Zainab Musa Dahuru, minor, Zangon Marikita, individually and as parent and natural guardian of Ismaila Musa, minor, Arhaji Muihammad Soja, individually and as parent and natural guardian and personal representative of Estate of Hamaza Achaji Muhammad, minor, deceased, Achaji Ibrahim Dankwalba, individually and as parent and natural guardian of Personal Representative of Est of Abdullahi Ibrahim, minor, Mallam Lawan, individually and as parent and natural guardian and personal representative of Est. of Aisha Lawan, minor, deceased, Alhaji Muhammed Tsohon Sojo, individually and as parent and

natural guardian and personal representative of Est. of Unni Alhasi Muhammed, minor, Ismaila Zubairui, individually and as parent and natural guardian and personal representative of Est. of Mustapha Zubairu, minor, Deceased, Abubaker Musa, individually and as parent and natural of Sa'adatu Musa, Minor, Mohamed Abdu, individually and as parent and natural guardian of Haruna Abdu, minor, Mallam Hassan, individually and as parent and natural guardian and personal representative of Est. of Sadiya Hassan, minor, deceased, Mallam Yakubu Umar, individually and as parent and natural guardian of, Mallam Samaila, individually and as parent and natural guardian of Adamu Samalia, minor, Musa Yahaya, individually and as parent and natural guardian of Ukhasa Musa, minor, Audu Ismailia Adamu, individually and as parent and natural guardian of Yashaya Samaila, Malam Musa Dahiru, individually and as parent, Malam Musa Zango, individually and as parent and natural guardian os Samaila Musa, minor, Mallam Alhassan Maihula, individually and as a parent and natural guardian of Najib Maihula, minor, Mallam Abdullah Gama, individually and as parent and natural guardian of Dankuma Gama, Minor, Dauda Nuhu, individually and as parent and natural guardian and personal representative of Est. of Hamisu Nuhu, minor, deceased, Mallam Abdullahi, individually and as parent and natural guardian and personal representative of Est. of Najaratu Adbullahi, minor, deceased, Malam Umaru Mohammed, individually and as parent and natural guardian and personal representative of Est. of Sule Mohammed, minor, deceased, Mallam Nasiru, individually and as parent and natural guardian and personal representative of Est. of Yusif Nasiru, mi-

nor, deceased, Yusuf Musa, individually and as parent and natural guardian and personal representative of Est. of Nafisatu Musa, minor, deceased, Mallam Muritala, individually and as parent and natural guardian and personal representative of Est. of Umaru Muritala, minor, deceased, Mallam Tanko, individually and as parent and natural guardian and personal representative of Est. of madina Tankol, minor deceased, Mallam Sheu, individually and as parent and natural guardian and personal representative of Est. of Madina Tankol, minor, deceased, Malam Kabiru Mohamed, individually and as parent and natural guardian and personal representative of Est. of Kabiru Mohamed, minor, deceased, Mallam Sule Abubakar, individually and as parent. and natural guardian and personal representative of Est. of Fatima Abubaker, minor, deceased, Mallam Idris, individually and as parent and natural guardian and personal representative of Est. of Baba Idris, minor, deceased, Mallam Mohamed Bashir, individually and as parent and natural guardian and personal representative of Est. of Sani Bashir, minor, deceased, Ibrahim, individually and as parent and natural guardian and personal representative of Est. Hassan Ibrahim, minor, deceased, Alhaji Shuaibu, individually and as parent and natural guardian and personal representative of Est. of Masjbatu Shuaibu, minor, deceased, Mallam Abdullahi Sale, individually and as parent and natural guardian and personal representative of Est. of Shamisiya Sale, minor, deceased, Mallam Ibrahim Amyarawa, individually and as parent and natural guardian and personal representative of Est. of Yahaya Ibrahim, minor, deceased, Mallam Abdu Abubaker, individually and as parent and natural guardian and per-

sonal representative of Est. of Nasitu Abubaker, minor, deceased, Mallam Yusuf, individually and as parent and natural guardian and personal representative of Est. of Hodiza Yusuf, minor, deceased, Mallam Dauda Yusuf, individually and as parent and natural guardian and personal representative of Est. of Abubaker Sheu, minor, deceased, Maliam Mohammed Sheu, individually and as parent and natural guardian and personal representative of Est. of Mustapha Yakubu, minor, deceased, Alhaji Ubah, individually and as parent and natural guardian and personal representative of Est. of Maryam Ubah, minor, deceased, Mallam Mohamadu Jabbo, individually and as parent and natural guardian of Auwalu Mohamadu, Mallam Abdullah Adamu, individually and as parent and natural guardian and personal representative of Est. of Abdullah Adamu, minor,

Plaintiffs-Appellants,

v

Pfizer, Inc.,

Defendant-Appellee.

**ORDER**

Docket Number:
05-4863-cv(L),
05-6768-cv(CON)

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Appellee Pfizer, Inc. having filed a petition for panel rehearing, or, in the alternative, for rehearing en banc, and the panel that determined the appeal having considered the request for panel rehearing, and the active members of the Court having considered the request for rehearing en banc,

IT IS HEREBY ORDERED that the petition is denied.

For the Court:

Catherine O'Hagan Wolfe, Clerk

By: s/ Frank Perez
Frank Perez, Deputy Clerk

## APPENDIX C

United States District Court,
S.D. New York.

Rabi ABDULLAHI, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatau Abdullahi, et al., Plaintiffs,

v.

PFIZER, INC., Defendant.
No. 01 Civ. 8118 (WHP).

Aug. 9, 2005.

*MEMORANDUM AND ORDER*

PAULEY, J.

This putative class action stems from Plaintiffs' allegations that they suffered grave injuries from an experimental antibiotic administered by defendant Pfizer, Inc. ("Pfizer" or "Defendant") in Nigeria. Plaintiffs bring their action under 28 U.S.C. § 1350, the Alien Tort Statute (the "ATS"),[1] because Pfizer

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[1] The Complaint refers to the ATS as the Alien Tort Claims Act ("ATCA"). Indeed, even courts disagree over the statute's proper name. *Compare Rasul v. Bush*, 542 U.S. 466, 124 S.Ct. 2686, 2691 (2004) ("Alien Tort Statute") *with Flores v. S. Peru Copper Corp.*, 414 F.3d 233, 2003 WL 24122601, at *1 (2d Cir. Aug. 29, 2003), *previously published as* 406 F.3d 65, *previously published as* 343 F.3d 140 (2d Cir. 2003) ("Alien Tort Claims Act"). This Court refers to the statute as the Alien Tort Statute, because it is purely jurisdictional in nature, and does not provide a private cause of action. *See Sosa v. Alvarez-*

purportedly violated the Nuremberg Code, the Declaration of Helsinki, article 7 of the International Covenant on Civil and Political Rights ("ICCPR"), FDA regulations and other customary international law.

On September 16, 2002, this Court dismissed this action on *forum non conveniens* grounds. *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118(WHP), 2002 WL 31082956 (S.D.N.Y. Sept. 17, 2002) ("*Abdullahi I*"). Thereafter, the Second Circuit remanded the action for consideration of the circumstances underlying dismissal of a related case in Nigeria, captioned *Zango v. Pfizer International, Inc.*, Case No. FHC/K/CS/204/2001 (the "*Zango* proceedings"), *Abdullahi v. Pfizer, Inc.*, No. 02-9223(L), 77 Fed. App'x 48, 53 (2d Cir. Oct. 8, 2003) ("*Abdullahi II*"). The parties submitted the record of the *Zango* proceedings for review in connection with the forum non conveniens analysis. In addition, Pfizer moves to dismiss for lack of subject matter jurisdiction under the ATS.

As discussed below, this Court grants Pfizer's motion to dismiss. In addition, this Court finds that the *Zango* proceedings do not preclude dismissal of this action for forum non conveniens.

## *BACKGROUND*

### I. *Brief Overview of the Alleged Facts*

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*Machain, et al.*, 542 U.S. 692, 124 S. Ct. 2739, 2761 (2004).

The factual background of this action is set forth in this Court's prior Memorandum and Order. See *Abdullahi I*, 2002 WL 31082956, at *1-3. Briefly stated, Plaintiffs are Nigerian minors and their guardians, residing in Nigeria. *Abdullahi I*, 2002 WL 31082956, at *1. The central events at issue in this lawsuit occurred in 1996, soon after epidemics of bacterial meningitis, measles and cholera broke out in Kano, Nigeria. *Abdullahi I*, 2002 WL 31082956, at *1. Pfizer established a treatment center at the Infectious Disease Hospital ("IDH") in Kano to treat meningitis victims. *Abdullahi I*, 2002 WL 31082956, at *1. Plaintiffs allege that instead of using safe and effective treatments, Pfizer embarked on a medical experiment involving the "new, untested and unproven" antibiotic, trovaflozacin mesylate, better known by its brand name, Trovan® ("Trovan"). *Abdullahi I*, 2002 WL 31082956, at *1.

"Plaintiffs further contend that Pfizer's sole purpose for traveling to Kano was to expedite the FDA's approval of Trovan to treat pediatric victims." Abdullahi I, 2002 WL 31082956, at *2. Nigerian officials allocated two IDH wards to Pfizer for the testing. Abdullahi I, 2002 WL 31082956, at *2. Pfizer treated children ranging in age from one to thirteen years who exhibited symptoms of neck stiffness, joint stiffness and high fevers with headaches and divided them into two groups. *Abdullahi I*, 2002 WL 31082956, at *2. One group was treated with Trovan, while the other was "purposefully 'low-dosed'" with ceftriaxone, an FDA-approved drug shown to be effective in treating meningitis. *Abdullahi I*, 2002 WL 31082956, at *2. To enhance the comparative results of Trovan, Pfizer administered only a third of cef-

triaxone's recommended dosage. *Abdullahi I*, 2002 WL 31082956, at *2.

Plaintiffs contend that "Pfizer failed to explain to the children's parents that the proposed treatment was experimental, that they could refuse it, or that other organizations offered more conventional treatments at the same site free of charge." *Abdullahi I*, 2002 WL 31082956, at *2. After two weeks of testing, Pfizer's team left Kano and never returned for follow-up evaluations. *Abdullahi I*, 2002 WL 31082956, at *2. Five children who received Trovan and six children who were "low-dosed" with ceftriaxone died, while others suffered paralysis, deafness and blindness. *Abdullahi I*, 2002 WL 31082956, at *2.

II. *Procedural History*

On August 29, 2001, Plaintiffs, who are Nigerian residents, brought this action under the ATS to recover damages for Pfizer's alleged violations of international law, specifically, the Nuremberg Code, the Declaration of Helsinki, the guidelines authored by the Council for International Organizations of Medical Services ("CIOMS"), article 7 of the ICCPR, the Universal Declaration of Human Rights and FDA regulations. (Complaint, dated Aug. 28, 2001 ("Compl.") ¶¶ 10, 15, 134, 228-50.) Plaintiffs allege that despite knowing that Trovan could cause serious joint and liver damage, Pfizer failed to inform them of that risk or seek their informed consent, and neglected to evaluate the subjects subsequent to their treatment. (Compl.¶¶ 135-40.) Pfizer moved to dismiss the Complaint for forum non conveniens and failure to state a claim. By Memorandum and Order

dated September 16, 2002, this Court denied Pfizer's motion to dismiss for failure to state a claim but granted its motion to dismiss on forum non conveniens grounds. *Abdullahi I*, 2002 WL 31082956, at *6, 12. This Court found that the action should be litigated in Nigeria where the alleged incidents took place. *Abdullahi I*, 2002 WL 31082956, at *12. Plaintiffs appealed that ruling to the Court of Appeals.

On appeal, Plaintiffs asked the Second Circuit to take judicial notice of the fact that a parallel action filed in Nigeria, involving different plaintiffs but the same course of conduct by Pfizer, was voluntarily dismissed on August 19, 2002.[2] *Abdullahi II*, 77 Fed. App'x at 52. In particular, "Plaintiffs request[ed] that [the Second Circuit] notice both the fact of the dismissal 'and the reasons for it.'" *Abdullahi II*, 77 Fed. App'x at 52. Plaintiffs argued that the *Zango* plaintiffs' Notice of Discontinuance evidences their reasons for discontinuing the action: "The notice blames an indefinite adjournment and the fact that the judge hearing the case declined jurisdiction 'for personal reasons.'" *Abdullahi II*, 77 Fed. App'x at 52.

Pfizer objected to Plaintiffs' request, and asked that the Second Circuit take notice of "the entire *Zango* docket, minutes and rulings because, according to Pfizer, these entries, minutes and rulings show that the *Zango* plaintiffs' version of events (as outlined in the Notice of Discontinuance) is disingenuous." *Abdullahi II*, 77 Fed. App'x at 52.

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[2] While "[t]he Zango plaintiffs' Notice of Discontinuance was dated August 19, 2002, ... it was not actually filed until October 17, 2002." *Abdullahi*, 77 Fed. App'x at 52 n. 2.

Because the parties' understanding of the *Zango* proceedings conflicted and the *Zango* record was not before this Court, the Second Circuit declined to take judicial notice of the matters requested by either side. The Court of Appeals noted that "[t]hese facts ... would seem to be relevant to the *forum non conveniens* analysis-perhaps providing just the type of specific information that the District Court found lacking," and "remand[ed] the case to the District Court for proceedings to determine what precipitated the dismissal in *Zango* and to evaluate whether that impacts the District Court's forum non conveniens analysis." *Abdullahi II*, 77 Fed. App'x at 53.

On September 8, 2004, this Court held oral argument on the issue framed by the Court of Appeals. At the oral argument, Pfizer sought permission to file a brief on the impact of the Supreme Court's ruling in *Sosa v. Alvarez-Machain* and the Second Circuit's ruling in *Flores v. Southern Peru Copper Corporation* in support of a new motion to dismiss for failure to state a claim under the ATS. (Transcript of Oral Argument, dated Sept. 8, 2004 ("Tr.") at 28-30.) To ensure "judicial economy," this Court agreed to consider the impact of *Sosa* and *Flores* on the instant action. (Tr. at 29.)

III. *Zango Proceedings*

The facts pertaining to the Zango proceedings are gleaned from the declarations of the parties' experts. (See Affidavit of Lukman O. Ishola, dated June 3, 2003 ("Ishola Aff. I"); Affidavit of Lukman O. Ishola, dated May 7, 2004 ("Ishola Aff. II"); Declaration of

Adetunji Oyeyipo, dated Apr. 29 2004 ("Oyeyipo Decl.").)

On March 12, 2001, the *Zango* plaintiffs, represented by Lukman O. Ishola, brought their action in the Federal High Court in Kano, Nigeria, seeking "compensation for losses suffered and the death of some of the [*Zango* ] [p]laintiffs as a result of the injuries sustained upon the administration of the drug Trovafloxacin (Trovan)." (Ishola Aff. I ¶ 1, 3; see Ishola Aff. II ¶ 1; Oyeyipo Decl. ¶ 10.) The *Zango* complaint alleged that there were 350 class members. (Oyeyipo Decl. ¶ 10; Ishola Aff. II ¶ 3.) In addition to Pfizer, the *Zango* plaintiffs named the Federal Ministry of Health, the Minister of Health, and the Attorney General and Minister of Justice of Nigeria (collectively, the "Government Defendants") as defendants. (Oyeyipo Decl. ¶ 10; Oyeyipo Decl. Ex. A at 97-99.)

The parties dispute whether the Kano action progressed in a timely manner. For example, Plaintiffs contend that it "suffered 14 adjournments without appreciable progress" (Ishola Aff. I ¶ 5), while Pfizer contends that the *Zango* court "gave considerable attention to the matter, holding eight separate Court dates in the course of over a year, and more recently holding a ninth hearing approximately two months after a new judge was appointed." (Oyeyipo Decl. ¶ 5; Oyeyipo Decl. Ex. A: Record of the *Zango* Proceedings.) The *Zango* record indicates that some of the adjournments in that action resulted from failure of the *Zango* plaintiffs or their counsel to appear in court or from adjournments they requested. (*See, e.g.*, Oyeyipo Decl. Ex. A at 175 (plaintiffs' counsel not present), 175-76 (plaintiffs' counsel seeks ad-

journment), 187 (plaintiffs' counsel seeks adjournment).)

Additionally, the *Zango* plaintiffs appear to have pursued litigation strategies that further delayed the proceedings. For example, in their Answer, the Nigerian Government defendants argued that the Public Officers Protection Act Cap 379 Law of the Federation of Nigeria 1990 barred the suit against them. (Oyeyipo Decl. Ex. A at 95.) In response, the *Zango* plaintiffs requested "a short date to allow [its counsel] to react and argue the objection" of the Government Defendants. (Oyeyipo Decl. Ex. A at 176.) The case was adjourned to July 3, 2001. (Oyeyipo Decl. Ex. A at 176.) On July 3, 2001, instead of addressing the merits of the Government Defendants' opposition, the *Zango* plaintiffs objected that the Government Defendants had not filed "a memo of appearance in this matter" and urged that the defense be "struck out." (Oyeyipo Decl. Ex. A at 176.) Pfizer's counsel responded that "one would have expected [the *Zango* plaintiffs] to overlook any [technical] irregularity so as to give [their] suit a speedy trial," and "urge[d] the court to over rule the objection of [the *Zango* plaintiffs] and to allow parties to address the Court on the issue of preliminary objection filed by the [Government] Defendants."(Oyeyipo Decl. Ex. A at 180.) While the court declined the Zango plaintiffs' request to strike the defense, it adjourned the proceeding to allow the Government Defendants' counsel an opportunity to "apply formally to regularize his position in th[e] matter."(Oyeyipo Decl. Ex. A at 181-82.) On September 24, 2001, instead of responding to the Government Defendants' defense, the *Zango* plaintiffs asked the court to "strike out" their action against the Government De-

fendants. (Oyeyipo Decl. Ex. A at 183.) Because there was no objection, the court dismissed the action against the Government Defendants but ordered the *Zango* plaintiffs to pay N3,000 (three thousand naira) in costs. (Oyeyipo Decl. Ex. A at 184-85.)

On November 5, 2001, the *Zango* plaintiffs sought leave to amend their statement of claim and the court granted the request. (Oyeyipo Decl. Ex. A at 186-87.) However, the *Zango* plaintiffs did not file an amended statement of claim. There is also evidence that the *Zango* plaintiffs repeatedly failed to adequately respond to Pfizer's requests for particulars. (Oyeyipo Decl. Ex. A at 112-13, 153-64, 187, 189-90.)

Plaintiffs argue that Pfizer bears responsibility for delays in the *Zango* proceeding. (Ishola Aff. I ¶¶ 6-7.) In particular, Ishola contends that Pfizer "filed an application for the supply of further and better particulars on August 6, 2001 and I verily believe that learned Counsel deliberately left it in abeyance for argument until June 6, 2002." (Ishola Aff. I ¶ 6.) Ishola further states that he "verily believe[s] that [Pfizer's] Counsel, Messrs Rotimi Ogunesho and Tunji Oyeyipo who usually appeared in court were never ready to argue the motion filed on August 6, 2001 for 11 months after filing the application until the [Pfizer's] leading counsel learned Senior Advocate of Nigeria, Alhaji Abdullahi Ibrahim deemed it fit to appear for the first time since the commencement of the Suit on 12th March, 2001 and argue[ ]" the motion. (Ishola Aff. I ¶ 7.) However, both assertions, admittedly Ishola's "beliefs," are unsupported by evidence.

There is no dispute that some of the delay in the *Zango* proceedings resulted from the Nigerian judici-

ary. For example, on July 30, 2001, the case was adjourned until September 24, 2001 because Judge Nwaogwugwu, the assigned judge, was unavailable for personal reasons. (Oyeyipo Decl. ¶ 25 & Ex. A at 183.) Later, in November 2001, Judge Nwaoagwugwu was removed from the bench because he had "assumed jurisdiction over a[n unrelated] case that he did not have the authority to adjudicate over."(Oyeyipo Decl. ¶ 43; *see also* Letter to the Court from Elaine S. Kusel, dated May 7, 2004 ("Kusel Letter") at 4.) Subsequently, on April 22, 2002, Judge Hobon was assigned the Zango action. (Oyeyipo Decl. Ex. A at 188; *see also* Kusel Letter at 4.) Less than three months later, Judge Hobon declined jurisdiction over the action for "reasons personal" to him and transferred the action back to "Court I" where the action had originated. (Oyeyipo Decl. Ex. B: Ruling By Judge Hobon, dated July 4, 2002 at 8.)

On August 19, 2002, after Judge Hobon's recusal, the *Zango* plaintiffs prepared a Notice of Discontinuance, but did not file it with the High Court until October 17, 2002. (Oyeyipo Decl. Ex. A at 170; *see also* Ishola Aff. I ¶ 16; Ishola Aff. II ¶ 10.) The *Zango* plaintiffs noted:

> The Plaintiffs hereby wholly discontinue this action against the Defendants.
>
> This notice is premised on the fact that the case has been adjourned indefinitely since the 4th of July 2002 by Hon. Justice Haroun Adamu of the Federal High Court 2, Kano having declined jurisdiction in this matter for personal reasons.

(Oyeyipo Decl. Ex. A at 170.)

IV. *Allegations of Corruption*

Plaintiffs contend that the *Zango* plaintiffs filed their Notice of Dismissal because after Judge Hobon's recusal no new judge was appointed in Kano. (Ishola Aff. II ¶ 10.) While Plaintiffs concede that "[i]t may be impossible to know with certainty what 'personal' reasons induced Justice Hobon to decline jurisdiction over the *Zango* case," they suggest that "corruption and bias in the Nigerian judiciary" played a role in the *Zango* plaintiffs' filing of their Notice of Dismissal. (Kusel Letter at 3-5.) However, Plaintiffs' contention is unsupported by any evidence. Indeed, Ishola does not contend that "corruption and bias in the Nigerian judiciary" played any role in his decision to file the Notice of Dismissal, but instead credits delay in the *Zango* proceedings. (Ishola Aff. II ¶ 10.)

Relying upon its submission in opposition to Pfizer's original motion to dismiss, Plaintiffs paint a picture of the Nigerian judiciary as corrupt and biased. (Kusel Letter at 3.) Plaintiffs further contend that "judges have been known to withdraw from cases for personal reasons when they are being subject to undue pressure or harassment to rule in a particular direction."(Kusel Letter at 4.) Plaintiffs also contend that Pfizer engaged in "bribery of judicial or law enforcement officials":

> [W]hen Pfizer conducted the Trovan testing in Kano, a Pfizer employee in Kano, Mike Dunn, suddenly contacted Pfizer headquarters and informed Dr. Scott Hopkins's secretary that the Nigerian government had

> halted the testing. According to Dr. [Juan] Walterspiel, Dunn stated that it was imperative that Pfizer immediately supply him with cash, or else he and other members of the Pfizer team would go to jail. Ultimately, no Pfizer employees were jailed and the tests continued.

(Kusel Letter at 4 (internal citations omitted).) Plaintiffs argue that these facts provide "strong circumstantial evidence that Justice Hobon declined jurisdiction because he was subject to improper or undue pressure, perhaps from Pfizer itself, or from government officials friendly with Pfizer who had been involved with the Trovan tests." (Kusel Letter at 4-5.)

## *DISCUSSION*

### I. *Rule 12(b)(6) Standard*

On a motion to dismiss pursuant to Rule 12(b)(6), a court typically must accept the material facts alleged in the complaint as true and construe all reasonable inferences in a plaintiffs favor. *Grandon v. Merrill Lynch & Co.*, 147 F.3d 184, 188 (2d Cir. 1998). A court should not dismiss a complaint for failure to state a claim unless "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957); *Gant v. Wallingford Bd. of Educ.*, 69 F.3d 669, 673 (2d Cir. 1995). Although on a motion to dismiss a court is generally limited to examining the sufficiency of the pleadings, where, as here, a challenge is directed at the court's subject matter jurisdiction, the

court may examine materials outside the complaint to resolve jurisdictional issues. *See Flores*, 2003 WL 24122601, at *18 n. 30; *Filetech S.A. v. France Telecom S.A.*, 157 F.3d 922, 932 (2d Cir. 1998); *In re South African Apartheid Litig.*, 346 F. Supp. 2d 538, 546 (S.D.N.Y. 2004).

II. *Claims Under the ATS*

Plaintiffs rely on the Nuremberg Code, the Declaration of Helsinki, article 7 of the ICCPR and "other norms of international law" to frame their complaint. (Compl.¶¶ 10, 15, 134.) In particular, Plaintiffs allege: "Foremost among Pfizer's violations was its failure to get any consent, informed or otherwise, before performing medical experiments on the subject children, in contravention of customary international law and as specifically forbidden by the Nuremberg Code, the Declaration of Helsinki, and the [ICCPR]." (Compl.¶ 10.) In Abdullahi I, because the parties had not argued "whether the [alleged] conduct qualifies as a violation of 'customary international law' under the [ATS]," this Court did not address that issue. *Abdullahi II*, 77 Fed. App'x at 53.

Pfizer presently moves to dismiss for failure to state a claim and lack of subject matter jurisdiction in light of "recent Supreme Court and Second Circuit decisions that sharply curtail claims under the Alien Tort Statute."(Pfizer's Memorandum in Support of its Motion to Dismiss, dated Oct. 1, 2004 ("Pfizer's Supp. Mem.") at 1 (citing *Sosa*, 542 U.S. 692, 124 S. Ct.

2739; *Flores*, 2003 WL 24122601).[3]) Although this Court could bypass the question of jurisdiction and dismiss the action solely on *forum non conveniens* grounds, *see Monegasque De Reassurances S.A.M. v. Nak Naftogaz of Ukr.*, 311 F.3d 488, 497-98 (2d Cir. 2002), for the sake of "judicial economy" this Court considers whether it has subject matter jurisdiction under the ATS. (Tr. at 29.)

A. *The Alien Tort Statute*

Adopted in 1789 by the first Congress, the ATS provides that "[t]he district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." 28 U.S.C. § 1350; *see also Flores*, 2003 WL 24122601, at *6. Here, Plaintiffs are aliens who allege tort causes of action. Thus, for federal subject matter jurisdiction to exist under the ATS, the complaint must adequately plead a violation of international law. *See Kadic v. Karadzic*, 70 F.3d 232, 238 (2d Cir. 1995) ("Because the [ATS] requires that plaintiffs plead a 'violation of the law of nations' at the jurisdictional threshold, this statute requires a more searching review of the merits to establish jurisdiction than is required under the more flexible 'arising under' formula of section 1331 [federal question jurisdiction]." (quoting *Filartiga v. Pena-Irala*, 630 F.2d 876, 887-88 (2d Cir. 1980))); *see also Bigio v. Coca-Cola Co.*, 239 F.3d 440, 447 (2d

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[3] While *Flores* preceded the Supreme Court's *Sosa* decision, its rationale conforms with *Sosa*'s.

Cir. 2000) (under the ATS, pleading a violation of the law of nations is a jurisdictional prerequisite).

"The [ATS] permits an alien to assert a cause of action in tort for violations of a treaty of the United States and for violations of the law of nations, which ... refers to the body of law known as customary international law." *Flores*, 2003 WL 24122601, at *11 (internal quotation marks omitted). Prior to *Sosa*, a number of courts-though not all-had held that the ATS created a cause of action. *See Flores*, 2003 WL 24122601, at *7 ("[T]he *Filartiga* Court not only held that the [ATS] provides a jurisdictional basis for suit, but also recognized the existence of a private right of action *for aliens only* seeking to remedy violations of customary international law."(emphasis in original)); *Abebe-Jira v. Negewo*, 72 F.3d 844, 847 (11th Cir. 1996) ("We read the [ATS] as requiring no more than an allegation of a violation of the law of nations in order to invoke section 1350."); *In re Estate of Ferdinand Marcos, Human Rights Litig.*, 25 F.3d 1467, 1475-76 (9th Cir. 1994) ("*Marcos*") (the ATS "creates a cause of action" and "nothing more than a *violation* of the law of nations is required to invoke section 1350" (internal quotation marks omitted)). *Cf. Tel-Oren v. Libyan Arab Republic*, 726 F.2d 774, 798 (D.C. Cir. 1984) (Bork, J., concurring) (noting that the ATS provides only subject matter jurisdiction-it does not create a cause of action); *see also Al Odah v. United States*, 321 F.3d 1134, 1146 (D.C. Cir. 2003) (Randolph, J., concurring). The Supreme Court addressed this dispute in *Sosa*, 542 U.S. 692, 124 S. Ct. 2739.

B. *The Sosa Case*

In *Sosa*, the plaintiff, Humberto Alvarez-Machain ("Alvarez"), a Mexican citizen, was indicted by a federal grand jury for the murder of a U.S. Drug Enforcement Agency ("DEA") agent in Mexico, and a federal court issued a warrant for his arrest. *Sosa*, 124 S. Ct. at 2746. "[T]he DEA approved a plan to hire Mexican nationals to seize Alvarez and bring him to the United States for trial." *Sosa*, 124 S. Ct. at 2746. "[A] group of Mexicans, including petitioner Jose Francisco Sosa, abducted Alvarez from his house, held him overnight in a motel, and brought him by private plane to El Paso, Texas, where he was arrested by federal officers." *Sosa*, 124 S. Ct. at 2746. Alvarez was then prosecuted and acquitted of the crime. *Sosa*, 124 S. Ct. at 2746.

After returning to Mexico, Alvarez filed suit in the Central District of California against Sosa and others under the Federal Tort Claims Act, 28 U.S.C. § 2674, and the ATS "for a violation of the law of nations." *Sosa*, 124 S. Ct. at 2747. Sosa contended that the ATS claim should be dismissed because the statute only provided federal courts with jurisdiction, and not a right of action without further congressional approval. Alvarez countered that the ATS authorizes creation of a new cause of action for torts that violate international law.

The Supreme Court, however, found Alvarez's reading "implausible" and held that the ATS was jurisdictional "in the sense of addressing the power of the courts to entertain cases concerned with a certain subject." *Sosa*, 124 S. Ct. at 2755. That is, the Court held that the ATS creates no new causes of action but confers on federal courts the power to hear a narrow set of alien tort claims for violations of inter-

national law. *Sosa*, 124 S. Ct. at 2755 (noting that because the ATS was placed in Section 9 of the Judiciary Act, "a statute otherwise exclusively concerned with federal-court jurisdiction," the ATS confers jurisdiction without itself creating a new cause of action).

Notwithstanding its holding, the Court left the door "ajar" to some international human rights litigation in federal courts, "subject to vigilant doorkeeping" by the courts. *Sosa*, 124 S. Ct. at 2764. The Court noted that courts may recognize new actionable rules based on evolving principles of international law. *Sosa*, 124 S. Ct. at 2764. However, federal courts "should require any claim based on the present-day law of nations to rest on a norm of international character accepted by the civilized world and defined with a specificity comparable to the features of the 18th-century paradigms." *Sosa*, 124 S. Ct. at 2761-62. The Court provided context to the types of actions it had in mind by listing the three causes of action recognized under federal common law at the time the ATS was enacted: offenses against ambassadors; violations of safe conduct; and individual actions for piracy. *Sosa*, 124 S. Ct. at 2758-59, 2761. Thus, "federal courts should not recognize private claims under federal common law for violations of any international law norm with less definite content and acceptance among civilized nations than the historical paradigms familiar when § 1350 was enacted." *Sosa*, 124 S. Ct. at 2765 (citing *United States v. Smith*, 18 U.S. (5 Wheat.) 153, 163-180, n.a (1820)).

Applying its holding to the facts of the case, the Court found that Alvarez's brief detention, transfer

to custody of American authorities and prompt arraignment did not violate any norm of customary international law "so well defined as to support the creation of a federal remedy." *Sosa*, 124 S. Ct. at 2769. To hold otherwise, the Court noted, "would support a cause of action in federal court for any arrest, anywhere in the world, unauthorized by the law of the jurisdiction in which it took place." *Sosa*, 124 S. Ct. at 2768.

C. *Application of Sosa to This Case*

Plaintiffs bring this action pursuant to the ATS to recover damages for Pfizer's alleged violations of international law. (Compl.¶¶ 10, 15, 134, 228-50.) Aware that Trovan had the potential to cause serious joint and liver damage, plaintiffs allege that Pfizer failed to inform them of that risk or seek their informed consent, and treated them but neglected to evaluate them after their treatment. (Compl.¶¶ 135-40.) While this Court may disapprove of Pfizer's actions, it must apply established law-"not some normative or moral ideal." *In re South African Apartheid Litig.*, 346 F. Supp. 2d at 548 (citing *Planned Parenthood v. Casey*, 505 U.S. 833, 850 (1992) (joint opinion) ("Our obligation is to define the liberty of all, not to mandate our own moral code.")).

Plaintiffs correctly state that non-consensual medical experimentation violates the law of nations and, therefore, the laws of the United States. *See The Paquete Habana*, 175 U.S. 677, 700 (1900) ("International law is part of our law, and must be ascertained and administered by the courts of justice of appropriate jurisdiction as often as questions of right depending upon it are duly presented for their

determination."); *United States v. Brandt, (The Medical Case)*, 2 Trials of War Criminals Before the Nuremberg Tribunals Under Control of Council Law No. 10, at 181 (1949) (elaborating on the Nuremberg Code, which prohibits non-consensual medical experimentation). However, the law of nations does not itself create a right of action because it does not require any particular reaction to violations of law, and therefore whether and how the United States reacts to such violations are domestic questions. *See Marcos*, 25 F.3d at 1475 (internal quotation marks omitted); *see also Sosa*, 124 S. Ct. at 2754-55; *Kadic v. Karadzic*, 70 F.3d 232, 246 (2d Cir. 1995) ("The law of nations generally does not create private causes of action to remedy its violations, but leaves to each nation the task of defining the remedies that are available for international law violations.").

While federal courts have the authority to imply the existence of a private right of action for violations of *jus cogens* norms of international law, *Bivens v. Six Unknown Named Agents of the Fed. Bureau of Narcotics*, 403 U.S. 388, 392 (1971); *see Sosa*, 124 S. Ct. at 2744, federal courts must consider whether there exist "special factors counseling hesitation in the absence of affirmative action by Congress," *Bivens*, 403 U.S. at 396; *see Sosa*, 124 S. Ct. at 2763. "The determination of what offenses violate customary international law ... is no simple task." *Flores*, 2003 WL 24122601, at *11. Nonetheless, "[t]he law of nations 'may be ascertained by consulting the works of jurists, writing professedly on public law; or by the general usage and practice of nations; or by judicial decisions recognizing and enforcing that law.'" *Filartiga*, 630 F.2d at 880 (quoting *Smith*, 18 U.S. (5 Wheat) at 160-61); *see also United States v. Yousef*,

327 F.3d 56, 103 (2d Cir. 2003) ("[W]e look primarily to the formal lawmaking and official actions of States and only secondarily to the works of scholars as evidence of the established practice of States."). However, "in determining what offenses violate customary international law, courts must proceed with extraordinary care and restraint." *Flores*, 2003 WL 24122601, at *11; *Sosa*, 124 S. Ct. at 2763.

"[C]ustomary international law is composed only of those rules that States universally abide by, or accede to, out of a sense of legal obligation and mutual concern." *Flores*, 2003 WL 24122601, at *11; *see also Sosa*, 124 S. Ct. at 2767. In contrast, "[p]ractices adopted for moral or political reasons, but not out of a sense of legal obligation, do not give rise to rules of customary international law." *Flores*, 2003 WL 24122601, at *12. "[C]ustomary international law addresses only those 'wrongs' that are 'of *mutual*, and not merely *several*, concern' to States." *Flores*, 2003 WL 24122601, at *12 (quoting *Filartiga*, 630 F.2d at 888 (internal alterations omitted)). Matters of "mutual" concern between States involve States' actions performed towards or with regard to the other. *Flores*, 2003 WL 24122601, at *12. On the other hand, matters of "several" concern among States are those in which States are separately and independently interested. *Flores*, 2003 WL 24122601, at *12. Further, "[e]ven if certain conduct is universally proscribed by States in their domestic law, that fact is not necessarily significant or relevant for purposes of customary international law." *Flores*, 2003 WL 24122601, at *12-13. Indeed,

> the mere fact that every nation's municipal law may prohibit theft does not incorporate

> "the Eighth Commandment, Thou Shalt not steal'... (into) the law of nations." It is only where the nations of the world have demonstrated that the wrong is of mutual, and not merely several, concern, by means of express international accords, that a wrong generally recognized becomes an international law violation within the meaning of the statute.

*Filartiga*, 630 F.2d at 888 (quoting *IIT v. Vencap*, 519 F.2d 1001, 1015 (2d Cir. 1975)).

Here, the key question is whether this Court should infer the existence of a private right of action for the alleged violations of international law. In *Sosa*, the Supreme Court discussed "[a] series of reasons [that] argue for judicial caution when considering the kinds of individual claims that might implement the jurisdiction conferred by the early statute." *Sosa*, 124 S. Ct. at 2761-62. First, the prevailing conception of common law has changed since the ATS was enacted in 1789. While common law was once considered a "transcendental body of law" awaiting discovery, it is now understood that common law "is not so much found or discovered as it is either made or created" by the courts. *Sosa*, 124 S. Ct. at 2762. Second, federal common law requires federal courts to "look for legislative guidance before exercising innovative authority over substantive law." *Sosa*, 124 S. Ct. at 2762. Third, the creation of a private right of action should be left to the legislature. *Sosa*, 124 S. Ct. at 2762-63. Fourth, "the potential implications for the foreign relations of the United States of recognizing such causes should make courts particularly wary of impinging on the discretion of the Legislative and Executive Branches

in managing foreign affairs." *Sosa*, 124 S. Ct. at 2763. Finally, courts have no congressional mandate to "seek out and define new and debatable violations of the law of nations." *Sosa*, 124 S. Ct. at 2763.

An action lies under the ATS "only for violations of treaties or customary international law." *Flores*, 2003 WL 24122601, at *16; *see Sosa*, 124 S. Ct. at 2761-62. To state a claim under the ATS, a plaintiff must allege violation of a "clear and unambiguous" rule of customary international law. *Filartiga*, 630 F.2d at 884 (holding that because the prohibition on official torture is "clear and unambiguous," it can serve as a basis for suit under the ATS). As noted, Plaintiffs allege that their claims under the ATS are supported by international law as set forth in the Nuremberg Code, the Declaration of Helsinki, guidelines authored by the CIOMS, article 7 of the ICCPR and the Universal Declaration of Human Rights. (Compl.¶¶ 10, 15, 134, 228-50.) The sources of international law Plaintiffs rely on do not support jurisdiction under the ATS.

First, Plaintiffs contend that Pfizer's alleged actions violated the Nuremberg Code, which "sets forth the international standards of conduct governing biomedical research on human subjects." (Compl. ¶ 55; *see also* Compl. ¶¶ 10, 15.) The Nuremberg Code, however, does not give rise to a private right of action.[4]Document1zzB00442007098735 *See In re South*

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[4] Similarly, the FDA regulations do not provide any private right of action. *See Summit Tech., Inc. v. High-Line Med. Instruments Co.*, 933 F. Supp. 918, 932-33 (C.D. Cal. 1996); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997).

*African Apartheid Litig.*, 346 F. Supp. 2d at 550; *Ammend v. BioPort, Inc.*, 322 F. Supp. 2d 848, 872 (W.D. Mich. 2004) ("This Court agrees with other jurisdictions which have found that there is no private right of action for an alleged violation of international law for the protection of human research subjects under ... the Nuremberg Code."); *Robertson ex rel. Robertson v. McGee*, No. 01 CV 60, 2002 WL 535045, at *3 (N.D. Okla. Jan. 28, 2002). Further, the United States has not ratified or adopted the Nuremberg Code. *See Grimes v. Kennedy Krieger Inst.*, 366 Md. 29, 99 n. 39, 782 A.2d 807, 849 n. 39 (2001) ("[T]he Nuremberg Code ... [has] never been formally adopted by the relevant governmental entities."); *see also Ammend*, 322 F. Supp. 2d at 872 ("No Supreme Court decision ... has adopted the Nuremberg Code as constitutional law."). In fact, the Nuremberg Code has not been adopted by the international community, *see* George J. Annas & Michael A. Grodin, *Medical Ethics and Human Rights: Legacies of Nuremberg*, 3 Hofstra L. & Pol'y Symp. 111, 113-14 (1999) ("[T]he Nuremberg Code has never been formally adopted as a whole by the United Nations."); Evelyne Shuster, *Fifty Years Later: The Significance of the Nuremberg Code*, 337 N. Eng. J. Med. 1436, 1439 (1997) ("The Nuremberg Code has not been officially adopted in its entirety as law by any nation or as ethics by any major medical association."), evidencing that the Nuremberg Code "has not even been universally embraced by all of the prominent States." *Flores*, 2003 WL 24122601, at *19. Accordingly, this Court declines to find the Nuremberg Code a binding source of international law giving rise to a private cause of action under the ATS. *See Ammend*, 322 F. Supp. 2d at 872; *see also*

*Heinrich ex rel. Heinrich v. Sweet*, 49 F. Supp. 2d 27, 43 (D. Mass. 1999).

Plaintiffs further contend that Pfizer's alleged actions violated the Declaration of Helsinki of the World Medical Association and the CIOMS Guidelines. (Compl.¶¶ 10, 15, 62, 64.) However, "the Helsinki Accord does not create a private right of action in U.S. federal courts and do[es] not have the force of law." *Hoover v. W. Va. Dep't. of Health & Human Res.*, 984 F. Supp. 978, 980 (S.D. W.Va.), *aff'd*, 129 F.3d 1259 (4th Cir. 1997); *see also Ammend*, 322 F. Supp. 2d at 872 ("This Court agrees with other jurisdictions which have found that there is no private right of action for an alleged violation of international law for the protection of human research subjects under the Declaration of Helsinki."); *Robertson*, 2002 WL 535045, at *3. The Declaration of Helsinki, authored by the World Medical Association, is a "mere general statement of policy that is unlikely to give rise to obligations in any strict sense." *Flores*, 2003 WL 24122601, at *23 (internal quotation marks omitted). Indeed,

> a court is not granted a roving commission to pick and choose among declarations of public and private international organizations that have articulated a view on the matter at hand. Such declarations are almost invariably political statements-expressing the sensibilities and the asserted aspirations and demands of some countries or organizations-rather than statements of universally-recognized legal obligations. Accordingly, such declarations are not proper evidence of customary international law.

*Flores*, 2003 WL 24122601, at *23; *see also United States v. Yousef*, 327 F.3d 56, 102-03 (2d Cir. 2003) ("In a system governed by the rule of law, no private person-or group of men and women such as comprise the body of international law scholars-creates the law. Accordingly, instead of relying primarily on the works of scholars for a statement of customary international law, we look primarily to the formal lawmaking and official actions of States and only secondarily to the works of scholars as evidence of the established practice of States."); *Beanal v. Freeport-McMoran, Inc.*, 197 F.3d 161, 167-68 (5th Cir. 1999). Similarly, the CIOMS Guidelines are authored by "an international, non-governmental, nonprofit organization," *see What is CIOMS?*, http://www.cioms.ch/what_is_cioms.htm, and, therefore, fail to give rise to obligations in any strict sense. *See Flores*, 2003 WL 24122601, at *23-24; *Yousef*, 327 F.3d at 102-03; *Beanal*, 197 F.3d at 167-68. Further, like the Declaration of Helsinki, the broad aspirational language of the CIOMS Guidelines do not contain the specificity required under the ATS. See *Sosa*, 124 S. Ct. at 2761-62; *Flores*, 2003 WL 24122601, at *17 ("[I]n order to state a claim under the ATCA, we have required that a plaintiff allege a violation of a clear and unambiguous rule of customary international law."(internal quotation marks omitted)); *Beanal*, 197 F.3d at 167 (stating that customary international law cannot be established by reference to "abstract rights and liberties devoid of articulable or discernable standards and regulations"); *Marcos*, 25 F.3d at 1475 (stating that a rule of customary international law must be "specific, universal, and obligatory"). Finally, like the Declaration of Helsinki, the CIOMS Guidelines does not cre-

ate any legal obligations or binding rules that can be applied. *See Sosa*, 124 S. Ct. at 2767.

Plaintiffs also assert that Pfizer's failure to "get any consent, informed or otherwise, before performing medical experiments on the subject children" violates Article 7 of the ICCPR. (Compl.¶ 10.) "[A]lthough the [ICCPR] does bind the United States as a matter of international law, the United States ratified the Covenant on the express understanding that it was not self-executing[5] and so did not itself create obligations enforceable in the federal courts." *Sosa*, 124 S. Ct. at 2767. Indeed, "the Senate has expressly declined to give the federal courts the task of interpreting and applying international human rights law, as when its ratification of the [ICCPR] declared that the substantive provisions of the document were not self-executing." *Sosa*, 124 S. Ct. at 2763. Thus, Plaintiffs "cannot say that the ... [ICCPR] establish[es] the relevant and applicable rule of international law." *Sosa*, 124 S. Ct. at 2767; *see also In re South African Apartheid Litig.*, 346 F. Supp. 2d at 552-53; *Heinrich*, 49 F. Supp. 2d at 43 ("Because the United States Senate and all the courts to consider the issue have held that the Covenant is not self-executing and a private right of action should not be implied, the Plaintiffs have no recognized cause of action for civil responsibility for crimes against humanity."); *White v. Paulesen*, 997 F. Supp. 1380, 1386-87 (E.D. Wash. 1998) (finding that because the ICCPR was not self-executing, it did not

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[5] An act is self-executing if it is effective immediately without requiring additional action, legislation or legal steps.

give rise to a private right of action). Further, the ICCPR's vague language makes it difficult to "define or identify conduct that constitutes a violation of international law." Beanal, 197 F.3d at 168.

Finally, Plaintiffs rely upon the Universal Declaration of Human Rights. (Compl.¶¶ 246, 248.) "But the Declaration does not of its own force impose obligations as a matter of international law," and Plaintiffs cannot say that it "establish[es] the relevant and applicable rule of international law." *Sosa*, 124 S. Ct. at 2767. Like the Declaration of Helsinki and the CIOMS Guidelines, the Universal Declaration of Human Rights is "not [a] proper source [ ] of customary international law because [it is] merely aspirational and [was] never intended to be binding on member States of the United Nations." *Flores*, 2003 WL 24122601, at *21. Further, its language "is simply not specific enough to create binding legal rules." *In re South African Apartheid Litig.*, 346 F. Supp. 2d at 553 (citing *Flores*, 2003 WL 24122601, at *24-25 (finding that Universal Declaration's language regarding rights to health and life are too indefinite and express "virtuous goals" only)).

Because "a decision to create a private right of action is one better left to legislative judgment in the great majority of cases," *Sosa*, 124 S. Ct. at 2762-63, this Court will not judicially forge broad aspirational language into customary international law. As Judge Sprizzo poignantly noted:

> Besides the obvious difficulty of enforcing a principle that is so purposefully general in order that the greatest number of countries can agree while still disagreeing on the particulars of how to implement the goal, see

> Flores, 343 F.3d at 161, there is also the great problem that international agreements often set patently unattainable goals that cannot reasonably be considered legal obligations of those countries that hope to one day fulfill those aspirations. See, e.g., Kellogg-Briand Pact of 1928, 46 Stat. 2343 (1928) (renouncing war as an instrument of national policy and proclaiming that disputes will only be resolved by peaceful means).

*In re South African Apartheid Litig.*, 346 F. Supp. 2d at 553 n. 17. Indeed, "[w]hile the absence of congressional action addressing private rights of action under an international norm is more equivocal than its failure to provide such a right when it creates a statute, the possible collateral consequences of making international rules privately actionable argue for judicial caution." *Sosa*, 124 S. Ct. at 2763. As the Supreme Court cautioned,

> Whatever may be said for the broad principle [plaintiffs] advance[ ], in the present, imperfect world, it expresses an aspiration that exceeds any binding customary rule having the specificity we require. Creating a private cause of action to further that aspiration would go beyond any residual common law discretion we think it appropriate to exercise.

*Sosa*, 124 S. Ct. at 2769; *see also In re South African Apartheid Litig.*, 346 F. Supp. 2d at 554. A cause of action for Pfizer's "failure to get any consent, informed or otherwise, before performing medical experiments on the subject children" would expand customary international law far beyond that contemplated by the ATS. *Sosa*, 124 S. Ct. at 2761-62;

*see White*, 997 F. Supp. at 1385 n. 2 ("[T]his case appears to involve a situation where the principal substantive issue is whether Plaintiffs' consent to participate in the underlying experiments should be considered informed and voluntary.... Thus, this Court would be required to determine exactly what international law requires in the way of informed consent in this particular set of circumstances, an issue that is not directly addressed by any of the international law authorities cited by the parties.").

Accordingly, this Court finds that none of the sources of international law on which Plaintiffs advance provide a proper predicate for jurisdiction under the ATS.

III. *Forum Non Conveniens*

"*Forum non conveniens* is a discretionary device permitting a court in rare instances to 'dismiss a claim even if the court is a permissible venue with proper jurisdiction over the claim.'" *Wiwa v. Royal Dutch Petroleum Co.*, 226 F.3d 88, 100 (2d Cir. 2000) (quoting *PT United Can Co. v. Crown Cork & Seal Co.*, 138 F.3d 65, 73 (2d Cir. 1998)). The *forum non conveniens* analysis has two prongs. First, the defendant must demonstrate that an adequate alternative forum exists. *Peregrine Myanmar Ltd. v. Segal*, 89 F.3d 41, 46 (2d Cir. 1996); *see also Calavo Growers of Calif. v. Generali Belgium*, 632 F.2d 963, 968 (2d Cir. 1980) (*forum non conveniens* "presupposes that an alternative forum is available"). If an adequate alternate forum is available, the court then considers the public and private interest factors set forth in *Gulf Oil Corporation v. Gilbert*, 330 U.S. 501, 508-09

(1947), and its progeny. *See Bank of Credit & Commerce Int'l (Overseas) Ltd. v. State Bank of Pak.*, 273 F.3d 241, 246 (2d Cir. 2002); *Wiwa*, 226 F.3d at 100. From those factors, a court must determine whether a trial in the plaintiff's chosen forum would either create "oppressiveness and vexation to a defendant ... out of all proportion to plaintiff's convenience," or whether the "chosen forum [is] inappropriate because of considerations affecting the court's own administrative and legal problems." *Piper Aircraft v. Reyno*, 454 U.S. 235, 241 (1981) (internal quotation marks omitted). After considering the "private interest factors" concerning the convenience of the litigants, and "public interest factors" affecting the convenience of the forum, a "court may, in the exercise of its sound discretion, dismiss the case." *Piper Aircraft*, 454 U.S. at 241.

The Second Circuit remanded this action on the question of whether Nigeria is an "adequate alternative forum" in light of the *Zango* proceedings. Accordingly, this Court limits its *forum non conveniens* analysis to the adequacy inquiry.

A. *Adequate Alternative Form*

Pfizer asserts that Kano's Federal High Court is an adequate alternative forum for Plaintiffs' claims. Plaintiffs counter that Kano's Federal High Court lacks adequate procedural safeguards and that the Nigerian judiciary is known for rampant corruption and bias.

The requirement of an adequate alternative forum "[o]rdinarily ... will be satisfied when the defendant is 'amenable to process' in the other

jurisdiction." *Piper Aircraft*, 454 U.S. at 255 n. 22 (quoting *Gilbert*, 330 U.S. at 506-07). Further, "[a]n agreement by the defendant to submit to the jurisdiction of the foreign forum can generally satisfy this requirement." *DiRienzo v. Philip Servs. Corp.*, 232 F.3d 49, 57 (2d Cir.2000), *vacated on other grounds*, 294 F.3d 21 (2d Cir.2002); *accord Aguinda v. Texaco, Inc.*, 303 F.3d 470, 476-77 (2d Cir. 2002); *Albert Trading, Inc. v. Kipling Belg. N.V./S.A.*, No. 00 Civ. 0478 (RMB), 2002 WL 272408, at *3 (S.D.N.Y. Feb. 26, 2002). Here, Pfizer has agreed to (i) litigate these claims (or their Nigerian equivalents) in Nigeria, (ii) accept service of process in Nigeria, and (iii) waive any *res judicata* and statute of limitations-based defenses that may have matured since the filing of the instant Complaints. (Transcript of Oral Argument, dated Sept. 8, 2004 ("Tr.") at 17.) *See also Abdullahi I*, 2002 WL 31082956, at *7. Further, "Nigerian law provides an alternative basis for recovery even if it does not recognize the specific claims plaintiffs allege in this action." *Abdullahi I*, 2002 WL 31082956, at *7; *see PT United Can Co.*, 138 F.3d at 74.

"In rare circumstances ... where the remedy offered by the other forum is clearly unsatisfactory, the other forum may not be an adequate alternative." *Piper Aircraft*, 454 U.S. at 254 n. 22; *see also Eastman Kodak Co. v. Kaviln*, 978 F. Supp. 1078, 1084 (S.D. Fla. 1997) ("the 'alternative forum is too corrupt to be adequate' argument does not enjoy a particularly impressive track record"). Here, citing to State Department reports, newspaper articles and proceedings from an unrelated case, Plaintiffs argue that Nigerian judiciary is too corrupt and biased to be considered an adequate alternative forum. (Kusel Letter at 3; Declaration of Elaine S. Kusel, dated

June 14, 2005 Exs. 2-3: Newspaper articles; Ishola Aff. II Ex. D: Proceedings from an unrelated case).) This Court disagrees.

In its prior decision, this Court rejected Plaintiffs' generalized allegations of corruption and bias. *See Abdullahi I*, 2002 WL 31082956, at *9-10; *see also Leon v. Million Air, Inc.*, 251 F.3d 1305, 1312 (11th Cir. 2001) (finding insufficient plaintiffs' affidavits documenting the shortcomings of Ecuador's legal system, including a lack of financial resources, the use of manual typewriters in 90 percent of the courts, the absence of computers in the trial courts, and congestion and delays illustrated by case filings of one thousand lawsuits per judge and at least one commercial case that was pending for 12 years) (Newman, J., sitting by designation); *Monegasque De Reassurances S.A.M. v. Nak Naftogaz of Ukr.*, 311 F.3d 488, 499 (2d. Cir. 2002) (rejecting State Department reports as "a basis for any conclusion that the courts of Ukraine constitute an inadequate alternative forum"); *El-Fadl v. Cent. Bank of Jordan*, 75 F.3d 668, 678 (D.C. Cir. 1996) (State Department report expressing "concern about the impartiality" of Jordanian courts did not suffice to make that forum inadequate); *Aguinda v. Texaco, Inc.*, 142 F. Supp. 2d 534, 544 (S.D.N.Y. 2001), *aff'd*, 303 F.3d 470 (2d Cir. 2002) (finding State Department reports containing "conclusory assertions as to the relative corruptibility or incorruptibility of Ecuadorian courts, with scant references to specifics, evidence, or application to the instant cases" to be of "little use"); *see also Blanco v. Banco Indus. de Venez., S.A.*, 997 F.2d 974, 982 (2d Cir. 1993) (political unrest in a foreign jurisdiction did not render the forum inadequate absent some showing that the unrest has had an adverse

effect on the judicial system there); *Gonzalez v. P.T. Pelangi Niagra Mitra Int'l*, 196 F. Supp. 2d 482, 487-88 (S.D. Tex. 2002) (plaintiffs' general accusations contained in "voluminous proof of corruption in the Indonesian judiciary-including newspaper articles, statements by prominent Indonesian politicians, the results of a survey conducted by the Partnership for Governance Reform in Indonesia, a World Bank report and statements by the United States government" failed to render Indonesia an inadequate forum). Thus, the key issue here is whether Plaintiffs have adduced sufficient evidence to establish that the *Zango* proceedings demonstrate the inadequacy of the Nigerian forum.

As noted, Ishola, the *Zango* plaintiffs' counsel does not contend that he dismissed the action because of corruption or bias in favor of Pfizer. Instead, he dismissed that action because the *Zango* plaintiffs "waited endlessly" for a new judge to replace Judge Hobon. (Ishola Aff. II ¶ 10.) Indeed, even Plaintiffs' counsel concedes that "[i]t may be impossible to know with certainty what 'personal' reasons induced Justice Hobon to decline jurisdiction over the *Zango* case."(Kusel Letter at 3-5; *see also* Tr. at 24 ("I can't stand before you saying I know completely what is going on in the Nigerian judiciary.").) Thus, Plaintiffs cannot establish corruption and bias in the *Zango* proceedings.

Moreover, Plaintiffs have not submitted any evidence to show that the Nigerian judiciary would be biased against its own citizens in "the kind of controversy here at issue." *Aguinda*, 142 F. Supp. 2d at 545. Indeed, Pfizer lost a case to Nigerian citizens in the Nigerian Federal High Court involving Viagra.

(Declaration of Steven Glickstein, dated June 14, 2004 ("Glickstein Decl.") Ex. 4: Decision in *Pfizer Specialties Ltd. v. Chyzolo Pharmacy Ltd.*, Suit No. FHC/L/CS/99, dated Feb. 13, 2001.) Most of Plaintiffs' submissions are "of little use" because "they largely consist[ ] (perhaps understandably) of broad, conclusory assertions as to the relative corruptibility or incorruptibility of the [Nigerian] courts, with scant reference to specifics, evidence, or application to the instant cases." *Aguinda*, 142 F. Supp. 2d at 544; *see also Monegasque De Reassurances*, 311 F.3d at 493 (generalized allegations of corruption are insufficient); *S.C. Chimexim S.A. v. Velco Enters. Ltd.*, 36 F. Supp. 2d 206, 214-15 (S.D.N.Y. 1999) (finding that "general ... assertions are not sufficient to create a genuine issue of fact that Romania's judicial system as a whole is devoid of impartiality or due process," despite evidence that Romanian courts were "far from perfect").

Indeed, Plaintiffs' only specific evidence concerning Pfizer's efforts to influence the judiciary comes from Ishola's affidavit and Dr. Walterspiel's declaration. Based on "one witness, Kabiru, a nurse who was utilized by Pfizer for the tests," Ishola contends that bribes were offered to Nigerian government officials to induce them to cooperate with Pfizer officials in the Kano treatment program. (Ishola Aff. II ¶ 14.) Because Ishola's information is hearsay and not based on his personal knowledge, this Court rejects it. *See Hollander v. Am. Cyanamid Co.*, 172 F.3d 192, 198 (2d Cir. 1999) (holding that a court may "strike portions of an affidavit that are not based upon the affiant's personal knowledge, contain inadmissible hearsay or make generalized and conclusory statements"); *see also* Fed. R. Evid. 602 ("A witness may

not testify to a matter unless evidence is introduced sufficient to support a finding that the witness has personal knowledge of the matter."); *Doe v. Nat'l Bd. of Podiatric Med. Exam'rs*, No. 03 Civ. 4034 (RWS), 2004 WL 912599, at *4 (S.D.N.Y. Apr. 29, 2004) (holding that a court may decline to consider those portions of an affidavit not based on personal knowledge); *Scott v. Reno*, No. 97 Civ. 5203 (RPP), 1998 WL 249178, at *3 (S.D.N.Y. May 18, 1998). In any event, Ishola does not contend that Kabiru's statement influenced Ishola's decision to dismiss the Zango action. *See* Fed. R. Evid. 401-02.

Relying on Dr. Walterspiel's declaration, Plaintiffs contend that Pfizer engaged in "bribery of judicial or law enforcement officials ."(Kusel Letter at 4.) However, Dr. Walterspiel does not state that Pfizer engaged in "bribery of judicial or law enforcement officials" and does not address the *Zango* proceedings. Further, during the Kano treatment program in 1996, Dr. Walterspiel was "employed as a pediatric research physician at Pfizer's Groton, Connecticut facility," not in Nigeria. (Walterspiel Decl. ¶ 1; *see also* Dunne Aff. ¶ 3 ("Dr. Walterspiel was not in Nigeria during the Kano treatment program," and, therefore, "has no first-hand knowledge of anything that happened in Nigeria.").) Dr. Walterspiel's declaration makes it abundantly clear that his allegations of bribery are speculative and not based on personal knowledge. For example, he states that he was present when Mary Hayden, secretary to Dr. Scott Hopkins, took a phone call from "Mike Dunn [sic], M.D., one of the Pfizer employees treating children on the trial in Kano."(Walterspiel Decl. ¶ 3.) While Dr. Walterspiel contends that Dr. Dunne was "very concerned" and asked for cash to be sent to Kano to

prevent him and other Pfizer employees from being jailed (Walterspiel Decl. ¶ 4-5), Dr. Walterspiel was not a participant in the telephone call. Further, Hayden, the participant in the telephone call, squarely contradicts Dr. Walterspiel's second-hand rendition of the conversation. (Affirmation of Mary Hayden, dated June 7, 2004 ("Hayden Aff.") ¶ 3 ("There was never a phone call that I participated in where Dr. Hopkins, Dr. Dunne or anyone else on the call suggested that Pfizer had to send cash to Kano in order to avoid any Pfizer employee being jailed."); *see also* Dunne Aff. ¶¶ 6-9.). Given these infirmities, this Court cannot credit Dr. Walterspiel's version of events. *See Hester v. Rich*, No. 03 Civ. 5714(DC), 2004 WL 1872296, at *8 n. 7 (S.D.N.Y. Aug. 19, 2004) (excluding statements based on speculation and hearsay); *see also Howley v. Town of Stratford*, 217 F.3d 141, 154-55 (2d Cir. 2000) (plaintiff's testimony that other co-workers told her of certain harassing statements likely inadmissible to prove that the statements were actually made); 4 Jack B. Weinstein & Margaret A. Berger, *Weinstein's Federal Evidence* § 702.04[5], at 702-57 (2d ed. 2001) ("Testimony based on guesswork, speculation, or conjecture is inadmissible.").

To the extent Plaintiffs contend that delay in the *Zango* proceedings led them to dismiss that action, this Court finds that that delay was only temporary. Plaintiffs concede that the *Zango* plaintiffs were not without options after Judge Hobon recused himself. They could have appealed Judge Hobon's "administrative transfer" of their suit to Court I. (Ishola Aff. II ¶ 12; Tr. at 5-6.) The temporary delay inherent in this option does not render Nigeria inadequate or compel denial of Pfizer's *forum non conveniens mo-*

*tion. See In re Union Carbide Corp. Gas Plant Disaster*, 634 F. Supp. 842, 848 (S.D.N.Y. 1986), *aff'd as modified*, 809 F.2d 195 (2d Cir. 1987) (dismissing for *forum non conveniens* despite "delays and backlog ... in Indian courts" and widespread "postponements and high caseloads" due to the fact that "India has approximately one-tenth the number of judges, per citizen, as the United States"); *see also Leon*, 251 F.3d at 1314 (evidence of Ecuadorian justice system's lack of financial resources, ratio of 1,000 cases per judge and at least one commercial case pending for 12 years was insufficient to demonstrate inadequacy of forum); *Broadcasting Rights Int'l Corp. v. Societe du Tour de France*, 708 F. Supp. 83, 85 (S.D.N.Y. 1989) ("Delays in an alternative forum's judicial system are not sufficiently harmful of due process to prevent dismissal on the ground of *forum non conveniens*." ). Moreover, as this Court has noted, part of the delay in the *Zango* proceedings resulted from the *Zango* plaintiffs' or their counsel's failure to appear in court, their requests for adjournments and their litigation strategy.

An alternative forum will be held inadequate only in those "rare circumstances" where it is "so clearly ... unsatisfactory that it is no remedy at all." *Piper*, 454 U.S. at 254 & n. 22. Based on the foregoing, this Court concludes that Nigeria is an available alternative forum for this litigation. *See United Bank for Afr., PLC v. Coker*, No. 94 Civ. 0655 (TPG), 2003 WL 22741575, at *4 (S.D.N.Y. Nov. 18, 2003) ("[T]here is no question that the Nigerian forum is adequate to

litigate" claims); *see also Baker Marine Ltd. v. Chevron Ltd.*, 191 F.3d 194, 197 (2d Cir. 1999).[6]

## *CONCLUSION*

For the foregoing reasons, this Court grants Pfizer's motion to dismiss the Complaint for failure to state a claim under the Alien Tort Statute. Even if this Court had subject matter jurisdiction, it would dismiss the action on *forum non conveniens* grounds for the reasons stated in Part III. This Court would condition dismissal on *forum non conveniens* grounds on the following grounds:

1. Defendant Pfizer consents to suit and acceptance of process in any suit plaintiffs file in Nigeria on the claims that are the subject of the instant suit;

2. Defendant Pfizer waives any statute of limitations defense that may be available to it in Nigeria;

3. Defendant Pfizer makes available for discovery and for trial, at its own expense, any documents, or witnesses, including retired employees, within Pfizer's control that are needed for a fair adjudication of the plaintiffs' claims; and

4. Defendant Pfizer will not act to prevent plaintiffs from returning to this Court if the Federal High Court in Nigeria declines to accept jurisdiction of this action, if it is filed in Nigeria within 60 days of the entry of this Order.

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[6] Because this Court grants Pfizer's motion to dismiss for failure to state a claim under the ATS and on *forum non conveniens* ground, this Court need not address the alternate grounds for dismissal that Pfizer advances.

The Clerk of the Court is directed to mark this case closed.

## APPENDIX D

United States District Court,
S.D. New York.

Ajudu Ismaila ADAMU et al., Plaintiffs,

v.

PFIZER, INC., Defendant.

No. 04 Civ. 1351 (WHP).

Nov. 8, 2005.

*MEMORANDUM AND ORDER*

PAULEY, District Judge.

Plaintiffs bring this putative class action seeking redress for injuries arising from the experimental administration of an antibiotic in Nigeria by defendant Pfizer, Inc. ("Pfizer" or "Defendant").[1] Plaintiffs

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[1] In a related action involving the same underlying facts as those alleged here, this Court held that the plaintiffs failed to establish subject matter jurisdiction and, in the alternative, that the action should be dismissed on *forum non conveniens* grounds because Nigeria is an adequate forum. This Court incorporates the facts and rationales of the decisions in that case. *See Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118 (WHP), 2002 WL 31082956 (S.D.N.Y. Sept. 17, 2002) (*"Abdullahi I"*), *vacated and remanded, Abdullahi v. Pfizer, Inc.*, No. 02-9223(L), 77 Fed. Appx. 48, 53 (2d Cir. Oct. 8, 2003) (*"Abdullahi II"*); *Abdullahi v. Pfizer, Inc.*, No. 01 Civ. 8118 (WHP), 2005 WL 1870811 (S.D.N.Y. Aug. 9, 2005) (*"Abdullahi III"* ). Familiarity with those decisions (collectively, *"Abdullahi"*) is presumed.

bring their action under 28 U.S.C. § 1350, the Alien Tort Statute (the "ATS"),[2] claiming that Pfizer violated the Nuremberg Code, the Declaration of Helsinki, the guidelines promulgated by the Council for International Organizations of Medical Services ("CIOMS"), article 7 of the International Covenant on Civil and Political Rights ("ICCPR"), Article 5 of the Universal Declaration of Human Rights and other customary international law as well as the FDA regulations. Plaintiffs also allege that Pfizer violated the Connecticut Unfair Trade Practices Act ("CUTPA") and the Connecticut Products Liability Act ("CPLA").

Defendants move to dismiss for failure to state a claim, lack of subject matter jurisdiction, and *forum non conveniens*. For the reasons discussed below, Pfizer's motion is granted.

## *BACKGROUND*

### I. *Brief Overview of the Facts*

The facts below are taken from Plaintiffs' one hundred and forty-five page complaint, initially filed in the District of Connecticut. Plaintiffs are Nigerian minors and their guardians, all of whom are residents of Nigeria. (Complaint, dated Nov. 27, 2002 ("Compl.") ¶ 7.) Pfizer is "one of the world's largest pharmaceutical companies and [a] world premier re-

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[2] The Complaint refers to the ATS as the Alien Tort Claims Act ("ATCA"). However, because the statute is purely jurisdictional in nature, and does not provide a private cause of action, this Court refers to it as the Alien Tort Statute. *Abdullahi III*, 2005 WL 1870811, at *1 n. 1.

search-based multinational pharmaceutical and health care company." (Compl.¶ 10.) Pfizer developed *Trovaflozacin Mesylate,* an antibiotic also known by the brand name "Trovan," at its Global Research and Development World Headquarters in Groton, Connecticut. (Compl.¶¶ 10, 13, 21.)

In early 1996, soon after an outbreak of cholera, meningitis and gastroenteritis in Nigeria, Pfizer sent a team of executives, scientists and doctors to the Infectious Disease Hospital ("IDH") in Kano to test Trovan on child patients. (Compl.¶¶ 7-8, 11.) *See Abdullahi I,* 2002 WL 31082956, at *1-2. Plaintiffs allege that Trovan was still "a new, untested and unproven drug." (Compl. ¶ 12; *see* Compl. ¶ 26.) Trovan was also known to have life-threatening side effects for children and adults. (Compl.¶ 13.) Prior animal testing indicated that Trovan might cause children to develop joint disease, abnormal cartilage growth and Osteochondrosis which could further cause improper bone formation and liver damage. (Compl.¶¶ 20, 24-25.) At the IDH, Pfizer selected "hundreds of Nigerian children" for participation in its experiments, but did not obtain the children's or their parents' informed consent. (Compl.¶¶ 12, 26.) Indeed, Pfizer did not inform the children or their parents that because Trovan was experimental, patients could refuse it and instead receive "proven safe and effective treatment." (Compl.¶ 12.)

At the treatment center, Pfizer divided the patients into two groups: half of the children were treated with Trovan while a control group was "intentionally low-dosed with an improperly adminis-

tered control drug Ceftriaxone."[3] (Compl.¶ 13.) That is, Pfizer administered the Ceftriaxone at one-third of its recommended dosage to enhance the comparative results of Trovan. (Compl.¶¶ 13, 29.) Further, Pfizer deviated from its testing protocol by not regularly analyzing the patients' blood specimens. As a result, Pfizer failed to assess the patients' reaction to Trovan until they exhibited specific observable permanent injuries. (Compl. ¶ 30.) At the time of the test, one of Pfizer's employees repeatedly informed Pfizer's senior management that its actions in Kano were oppressive, inappropriate and illegal. (Compl.¶ 23.)

Medecins Sans Frontieres ("MSF"), better known as Doctors Without Borders, was also treating IDH patients at this time. (Compl.¶ 15.) *See Abdullahi I*, 2002 WL 31082956, at *1. However, because of Pfizer's experimentation, the participating patients were denied adequate medical care and treatment they otherwise would have received from MSF. (Compl.¶ 15.) After two weeks of testing, Pfizer's team left Kano and never returned for follow-up evaluations. (Compl.¶ 27.) Many of the children who were administered Trovan or inadequate doses of Ceftriaxone died. (Compl.¶ 26.)

On November 27, 2002, Plaintiffs brought this action in the District of Connecticut, pursuant to the ATS and Connecticut statutes. Subsequently, the action was transferred to this Court as related to *Abdullahi v. Pfizer*, 01 Civ. 8118.

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[3] Ceftriaxone is an FDA-approved drug that has been shown as effective in treating meningitis. (Compl.¶ 29.) *See Abdullahi III*, 2005 WL 1870811, at *1.

II. *The* Abdullahi *Decisions*

On August 29, 2001, the *Abdullahi* plaintiffs, who were Nigerian residents, brought an action under the ATS against Pfizer for its alleged violations of international law, relying on the same sources of international law that Plaintiffs invoke in this action. The *Abdullahi* plaintiffs alleged that despite knowing that Trovan had the potential to cause serious joint and liver damage, Pfizer failed to inform them of that risk or seek their informed consent and neglected to evaluate the patients following their treatment. Pfizer moved to dismiss the complaint on *forum non conveniens* grounds and for failure to state a claim. By Memorandum and Order dated September 17, 2002, this Court denied Pfizer's motion to dismiss for failure to state a claim under the ATS, but granted its motion to dismiss on *forum non conveniens* grounds. *Abdullahi I*, 2002 WL 31082956, at *6-12. This Court held that the action should be litigated in Nigeria where the alleged incidents took place. *Abdullahi I*, 2002 WL 31082956, at *12. The *Abdullahi* plaintiffs appealed that ruling.

On appeal, the *Abdullahi* plaintiffs asked the Second Circuit to take judicial notice of the fact that a parallel action filed in Nigeria, *Zango v. Pfizer International, Inc.*, Case No. FHC/K/CS/204/2001 (Nigeria) (the "*Zango* proceedings"), involving different plaintiffs but the same course of conduct by Pfizer, was voluntarily dismissed on August 19, 2002.[4] *Ab-*

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[4] While "[t]he *Zango* plaintiffs' Notice of Discontinuance was dated August 19, 2002, ... it was not actually filed until October 17, 2002." *Abdullahi II*, 77 Fed.Appx. at 52 n. 2.

*dullahi II*, 77 Fed. Appx. at 52. In particular, the *Abdullahi* "[p]laintiffs request [ed] that [the Second Circuit] notice both the fact of the dismissal 'and the reasons for it.'" *Abdullahi II*, 77 Fed. Appx. at 52. The *Abdullahi* plaintiffs argued that the *Zango* plaintiffs' Notice of Discontinuance evidenced their reasons for discontinuing the action: "The notice blames an indefinite adjournment and the fact that the judge hearing the case declined jurisdiction 'for personal reasons.'" *Abdullahi II*, 77 Fed. Appx. at 52. Pfizer objected to the *Abdullahi* plaintiffs' request, and asked the Second Circuit to take notice of "the entire *Zango* docket, minutes and rulings," arguing that the full record demonstrated "that the *Zango* plaintiffs' version of events (as outlined in the Notice of Discontinuance) [was] disingenuous." *Abdullahi II*, 77 Fed. Appx. at 52.

Because the parties offered conflicting understandings of the *Zango* proceedings and had not submitted the *Zango* record for the Court's review, the Second Circuit declined to take judicial notice of the matters requested by either side. The Court of Appeals noted that the facts of the Nigerian case "would seem to be relevant to the *forum non conveniens* analysis-perhaps providing just the type of specific information that the District Court found lacking," and remanded the case to this Court "to determine what precipitated the dismissal in *Zango* and to evaluate whether that impacts the District Court's *forum non conveniens* analysis." *Abdullahi II*, 77 Fed. Appx. at 53.

In addition, the Court of Appeals noted that another panel of the Second Circuit had recently decided *Flores v. Southern Peru Copper Corp.*, 414 F.3d

233 (2d Cir. 2003), which held that claims of local, intranational environmental pollution were not actionable under the ATS because such pollution does not violate customary international law. However, because "Pfizer did not address [the ATS' applicability] before the District Court" and "[b]oth parties ha[d] glossed over the issue on appeal," the Second Circuit did not address whether it had jurisdiction under the ATS. *Abdullahi II,* 77 Fed. Appx. at 53.

On September 8, 2004, this Court held oral argument on the *forum non conveniens* issue framed by the Court of Appeals, and granted Pfizer's request to file a new motion to dismiss for the *Abdullahi* plaintiffs' failure to state a claim under the ATS. By Memorandum and Order dated August 9, 2005, this Court granted Pfizer's motion to dismiss because "none of the sources of international law [*Abdullahi*] Plaintiffs rel[ied] upon support[ed] jurisdiction under the ATS." *Abdullahi III,* 2005 WL 1870811, at *14. Further, this Court held that despite the record of the *Zango* proceedings, Nigeria was an adequate alternative forum for the litigation and dismissal on *forum non conveniens* grounds was warranted. *Abdullahi III,* 2005 WL 1870811, at *18.

## *DISCUSSION*

### I. *Motion to Dismiss Standard*

A court presented with a motion to dismiss under both Rule 12(b)(1) and 12(b)(6) must decide the "jurisdictional question first because a disposition of a Rule 12(b)(6) motion is a decision on the merits, and therefore, an exercise of jurisdiction." *Magee v. Nassau County Med. Ctr.,* 27 F. Supp. 2d 154, 158

(E.D.N.Y. 1998); *see also Rhulen Agency, Inc. v. Alabama Ins. Guar. Ass'n*, 896 F.2d 674, 678 (2d Cir. 1990). A motion to dismiss for subject matter jurisdiction under Rule 12(b)(1) is reviewed under the same standards as a motion to dismiss for failure to state a claim under Rule 12(b)(6). *Lerner v. Fleet Bank, N.A.*, 318 F.3d 113, 128 (2d Cir. 2003). On a motion to dismiss, a court typically must accept the material facts alleged in the complaint as true and construe all reasonable inferences in a plaintiffs' favor. *Grandon v. Merrill Lynch & Co.*, 147 F.3d 184, 188 (2d Cir. 1998). Although on a motion to dismiss a court is generally limited to examining the sufficiency of the pleadings, where, as here, a challenge is directed at the court's subject matter jurisdiction, the court may examine materials outside the complaint to resolve jurisdictional issues. *See Flores*, 414 F.3d at 255 n. 30; *Filetech S.A. v. France Telecom S.A.*, 157 F.3d 922, 932 (2d Cir. 1998); *In re S. African Apartheid Litig.*, 346 F. Supp. 2d 538, 546 (S.D.N.Y. 2004).

II. *Claims Under the ATS*

Plaintiffs rely on the Nuremberg Code, the Declaration of Helsinki, the guidelines authored by the CIOMS, article 7 of the ICCPR, Article 5 of the Universal Declaration of Human Rights and the FDA regulations to frame their ATS claim. (Compl.¶¶ 321-52.) Pfizer moves to dismiss for failure to state a claim and lack of subject matter jurisdiction under the ATS. While this action could be dismissed solely on *forum non conveniens* grounds, *see Monegasque De Reassurances S.A.M. v. Nak Naftogaz of Ukraine*, 311 F.3d 488, 497-98 (2d Cir. 2002), this Court also

considers the question of subject matter jurisdiction under the ATS for the sake of judicial efficiency.

The ATS does not itself create a private right of action. Rather, the statute provides district courts with "original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States." 28 U.S.C. § 1350; *see also Sosa v. Alvarez-Machain*, 542 U.S. 692, 698-99, 124 S. Ct. 2739, 2747, 159 L.Ed.2d 718 (2004); *Flores*, 414 F.3d at 237. "The [ATS] permits an alien to assert a cause of action in tort for violations of a treaty of the United States and for violations of the law of nations, which ... refers to the body of law known as customary international law." *Flores*, 414 F.3d at 247 (internal quotation marks omitted). Here, Plaintiffs are aliens who allege cognizable tort causes of action. Thus, for federal subject matter jurisdiction to exist under the ATS, the complaint must adequately plead a violation of international law. *See Kadic v. Karadzic*, 70 F.3d 232, 238 (2d Cir. 1995) ("Because the [ATS] requires that plaintiffs plead a 'violation of the law of nations' at the jurisdictional threshold, this statute requires a more searching review of the merits to establish jurisdiction than is required under the more flexible 'arising under' formula of section 1331 [federal question jurisdiction]." (quoting *Filartiga v. Pena-Irala*, 630 F.2d 876, 887-88 (2d Cir. 1980))); *see also Bigio v. Coca-Cola Co.*, 239 F.3d 440, 447 (2d Cir. 2000) (under the ATS, pleading a violation of the law of nations is a jurisdictional prerequisite).

Plaintiffs contend that Pfizer's non-consensual medical experimentation violated the law of nations, *i.e.*, customary international law. However, the law

of nations does not itself create a right of action because it does not prescribe a remedy. Whether and how the United States reacts to violations of international law are domestic questions that determine if a cause of action exists. *See In re Estate of Ferdinand Marcos, Human Rights Litig.*, 25 F.3d 1467, 1475 (9th Cir. 1994); *see also Sosa*, 124 S. Ct. at 2754-55; *Kadic*, 70 F.3d at 246 ("The law of nations generally does not create private causes of action to remedy its violations, but leaves to each nation the task of defining the remedies that are available for international law violations."). While federal courts have the authority to imply the existence of a private right of action for violations of *jus cogens* norms of international law, *see Sosa*, 124 S. Ct. at 2744, they must consider whether "special factors counseling hesitation in the absence of affirmative action by Congress" exist, *Bivens v. Six Unknown Named Agents of the Fed. Bureau of Narcotics*, 403 U.S. 388, 396, 91 S. Ct. 1999, 29 L.Ed.2d 619 (1971); *see Sosa*, 124 S. Ct. at 2763.

Here, the key question is should this Court infer the existence of a private right of action from the alleged violations of international law. An implied private action lies under the ATS "only for violations of treaties or customary international law." *Flores*, 414 F.3d at 253; *see Sosa*, 124 S. Ct. at 2761-62. Thus, because Pfizer is not alleged to have violated any treaty, to state a claim under the ATS, Plaintiffs must demonstrate violation of a "clear and unambiguous" rule of customary international law. *Filartiga*, 630 F.2d at 884 (holding that because the prohibition on official torture is "clear and unambiguous," it can serve as a basis for suit under the ATS). This Court has already discussed in *Abdullahi*

*III*, 2005 WL 1870811, at *11-14, why the sources of international law on which Plaintiffs rely do not create jurisdiction under the ATS. For the sake of brevity, this Court incorporates *Abdullahi III*'s analysis of the various sources of international law, and concludes that none of the sources of international law that Plaintiffs advance provide a proper predicate for jurisdiction under the ATS.[5]

III. *Claims Under the Connecticut Statutes*

Plaintiffs also bring Connecticut statutory claims under the CUTPA and the CPLA. (Compl.¶¶ 300-20.) Pfizer moves to dismiss these claims, arguing that under Connecticut choice of law principles, this action is governed by Nigerian law-not Connecticut statutes. Here, there is no dispute that Nigerian law affords redress for Plaintiffs' claims. (Compl.¶ 6(j).) *See Abdullahi III*, 2005 WL 1870811, at *3-5.

Because this action originated in the District of Connecticut, this Court as "the transferee district court [is] ... obligated to apply the state law that would have been applied if there had been no change of venue." *Van Dusen v. Barrack*, 376 U.S. 612, 639, 84 S. Ct. 805, 11 L.Ed.2d 945 (1964); *Chaiken v. VV Pub. Corp.*, No. 91 Civ. 2102 (JFK), 1991 WL 177269, at *2 (S.D.N.Y. Sept.4, 1991); *In re Union Carbide Corp. Gas Plant Disaster at Bhopal, India in December, 1984*, 634 F. Supp. 842, 866 (S.D.N.Y. 1986).

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[5] Because this Court does not have jurisdiction under the ATS, it declines to consider Pfizer's arguments regarding dismissal under Rule 12(b)(6) for failure to state a claim.

Thus, Connecticut choice of law principles apply to this action.

Connecticut adheres to the doctrine of *lex loci delicti,* under which the "substantive rights and obligations arising out of a tort controversy are determined by the law of the place of injury." *O'Connor v. O'Connor,* 201 Conn. 632, 637, 519 A.2d 13, 15 (1986); *accord Williams v. State Farm Mut. Auto. Ins. Co.,* 229 Conn. 359, 370-71, 641 A.2d 783, 789 (1994). However, where strict application of *lex loci delicti* would frustrate "the legitimate expectations of the parties" or undermine "an important policy of this state," Connecticut courts refuse to apply the doctrine. *O'Connor,* 201 Conn. at 637, 519 A.2d 13. *O'Connor* remains the leading case on this issue from the Connecticut Supreme Court. *O'Connor* involved an action by an automobile passenger against the driver for injuries arising from an out-of-state automobile accident. As described in a more recent decision, *O'Connor's* facts may be summarized as follows:

> Both parties were Connecticut domiciliaries but the accident occurred in Quebec, Canada. The principal issue was whether to apply the law of Quebec, which barred the plaintiff's action, or the law of Connecticut, which permitted it. The trial court applied the doctrine of lex loci delicti and granted the defendant's motion to strike the plaintiff's complaint. On appeal, [the Connecticut Supreme Court] substituted the "most significant relationship" analysis of §§ 6 and 145 of the Restatement [(Second) of the Conflict of Laws] ... for the doctrine of lex loci delicti.... After considering the Restatement factors, [the

> Connecticut Supreme Court] concluded that Connecticut had the closest relationship and the greatest interest in the disposition of the case. [It] therefore applied the law of Connecticut.

*Williams*, 229 Conn. at 371-72, 641 A.2d at 789.

Section 145 of the Restatement (Second) of Conflict of Laws provides that "[t]he rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6." Restatement (Second), Conflict of Laws § 145(1). Section 6, in turn, provides:

> (1) A court, subject to constitutional restrictions, will follow a statutory directive of its own state on choice of law.
>
> (2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include
>
> (a) the needs of the interstate and international systems,
>
> (b) the relevant policies of the forum,
>
> (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue,
>
> (d) the protection of justified expectations,
>
> (e) the basic policies underlying the particular field of law,

> (f) certainty, predictability and uniformity of result, and
>
> (g) ease in the determination and application of the law to be applied.

Restatement (Second), Conflict of Laws § 6. For assistance in evaluating the "policy choices set out in §§ 145(1) and 6(2) [of the Restatement]," a court should consider § 145(2) "which establishes black-letter rules of priority to facilitate the application of the principles of § 6 to tort cases." *O'Connor,* 201 Conn. at 652, 519 A.2d 13; *accord Dugan v. Mobile Medical Testing Services, Inc.*, 265 Conn. 791, 800-02, 830 A.2d 752, 760 (2003). That subsection provides:

> (2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:
>
> (a) the place where the injury occurred,
>
> (b) the place where the conduct causing the injury occurred,
>
> (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and
>
> (d) the place where the relationship, if any, between the parties is centered.
>
> These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Restatement (Second), Conflict of Laws § 145(2).

The alleged improper conduct is Pfizer's failure to inform the children or their parents about the potential problems with Trovan (Compl.¶ 12), and the administration of Trovan and low dosage of Ceftriaxone (Compl.¶¶ 13, 15, 26-27). Application of the § 145(2) factors suggests a strong case for applying Nigerian law because the Nigerian contacts to this litigation are stronger than Connecticut's. *See Williams,* 229 Conn. at 372, 641 A.2d at 789 (applying New York law where the accident happened in New York); *Norton v. Michonski,* 368 F. Supp. 2d 175, 179 (D. Conn. 2005) (applying Massachusetts law where automobile accident occurred in that state); *N. Tankers (Cyprus) Ltd. v. Backstrom,* 934 F. Supp. 33, 38-39 (D. Conn. 1996) (New York law applied because "the place of the injury ... [was] New York"); *Icelandic Coast Guard v. United Techs. Corp.,* 722 F. Supp. 942, 949 (D. Conn. 1989) (noting that "a strong case [could] be made for the application of Icelandic law," where the helicopter crash occurred off the coast of Iceland). First, Plaintiffs' injuries occurred in Nigeria. Second, Pfizer's alleged improper actions occurred in Nigeria. Third, Plaintiffs are Nigerian nationals and reside there; Pfizer, on the other hand, is a Delaware corporation with its headquarters in New York. (Compl.¶ 6.) Finally, Nigeria is the place where the parties' relationship is centered. Thus, factors (a), (b) and (d) point toward applying Nigerian law, while factor (c) is in equipoise.

Plaintiffs' sole basis for arguing that Connecticut law should govern is that Pfizer performed research and development with respect to Trovan and planned the Nigerian experiment in Connecticut. (Transcript of Oral Argument, dated Oct. 21, 2005, at 17-21.) However, this sole contact with Connecticut is insuf-

ficient to defeat the Nigerian interest in applying its own laws. *See Feldt v. Sturm, Ruger & Co.*, 721 F. Supp. 403, 404-05 (D. Conn. 1989) (holding that under *lex loci delecti*, Georgia law applies because "plaintiffs live[d] in Georgia, the gun in question was kept in Georgia, and the injury occurred in Georgia, even though the defendant's principal place of business was Southport, Connecticut", and the "handgun in question was manufactured by the defendant in Connecticut"); *see also N. Tankers Ltd.*, 934 F. Supp. at 39-40 ("[A]pplication of New York law here would be neither irrational nor arbitrary," or "produce an arbitrary or irrational result" because "[t]he place of the injury ... is New York," and "alleged damages ... were incurred in New York."); *Icelandic Coast*, 722 F. Supp. at 948.

Therefore, Nigerian-not Connecticut-substantive law governs, and Plaintiffs' claims under the CUTPA and the CPLA are dismissed.

IV. *Forum Non Conveniens*

"*[F]orum non conveniens* is a discretionary device permitting a court in rare instances to 'dismiss a claim even if the court is a permissible venue with proper jurisdiction over the claim.'" *Wiwa v. Royal Dutch Petroleum Co.*, 226 F.3d 88, 100 (2d Cir. 2000) (citing *PT United Can Co. v. Crown Cork & Seal Co.*, 138 F.3d 65, 73 (2d Cir. 1998)); *see Iragorri v. United Techs. Corp.*, 274 F.3d 65, 72 (2d Cir. 2001) (en banc). Dismissal is appropriate where "the balance of convenience tilts strongly in favor of trial in the foreign forum." *R. Maganlal & Co. v. M.G. Chem. Co.*, 942 F.2d 164, 167 (2d Cir.1991). First, the defendant

must demonstrate the existence of an adequate alternative forum. *Peregrine Myanmar Ltd. v. Segal*, 89 F.3d 41, 46 (2d Cir. 1996); *see also Calavo Growers of Calif. v. Generali Belgium*, 632 F.2d 963, 968 (2d Cir. 1980) (*forum non conveniens* "presupposes that an alternative forum is available"). If an adequate forum is available, the court then considers the public and private interest factors set forth in *Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508-09, 67 S. Ct. 839, 91 L.Ed. 1055 (1947), and its progeny. *See Bank of Credit & Commerce Int'l (OVERSEAS) Ltd. v. State Bank of Pakistan*, 273 F.3d 241, 246 (2d Cir. 2001); *Wiwa*, 226 F.3d at 100. Based on those factors, a court examines whether a trial in the plaintiff's chosen forum would create "oppressiveness and vexation to a defendant ... out of all proportion to plaintiff's convenience," or whether the "chosen forum [is] inappropriate because of considerations affecting the court's own administrative and legal problems." *Piper Aircraft v. Reyno*, 454 U.S. 235, 241, 102 S. Ct. 252, 70 L.Ed.2d 419 (1981) (internal quotation marks omitted). After considering the "private interest factors" concerning the convenience of the litigants and "public interest factors" affecting the convenience of the forum, a "court may, in the exercise of its sound discretion, dismiss the case." *Piper Aircraft*, 454 U.S. at 241, 102 S. Ct. 252.

A. *Adequate Alternative Forum*

Here, the parties have agreed to be bound by this Court's determination in *Abdullahi III* that an adequate alternate forum exists in Nigeria. (*See* Stipulation and Order, dated Mar. 18, 2005 (Docket No. 8).) In *Abdullahi I*, this Court held "in light of Pfizer's

showing that it is 'amenable to process' in Nigeria, and the conclusory nature of plaintiffs' evidence regarding the inadequacy of Nigeria's legal system, ... this [was] not one of those 'rare circumstances' where the potential difficulties of the foreign forum render the remedy offered by that forum 'clearly unsatisfactory.'" 2002 WL 31082956, at *10 (citing *Piper Aircraft*, 454 U.S. at 255 n. 22, 102 S. Ct. 252). In *Abdullahi III*, this Court concluded that the *Zango* dismissal did not impact the *forum non conveniens* analysis and that "Nigeria is an available alternative forum for this litigation." 2005 WL 1870811, at *18. Similarly, this Court finds that Nigeria is an available adequate alternate forum for this litigation.

B. Gilbert *Factors*

Because Nigeria provides an adequate alternative forum, this Court must weigh the *Gilbert* public and private interest factors to determine which forum "will be most convenient and will best serve the ends of justice." *Peregrine Myanmar*, 89 F.3d at 46; *accord Abdullahi I*, 2002 WL 31082956, at *10. The *Gilbert* public interest factors include (1) administrative difficulties associated with court congestion; (2) the unfairness of imposing jury duty on a community with no relation to the litigation; (3) the local interest in having localized controversies decided at home; and (4) avoiding problems in conflict of laws and the application of foreign law. *Gilbert*, 330 U.S. at 508-09, 67 S. Ct. 839; *Iragorri*, 274 F.3d at 74. The *Gilbert* private interest factors include (1) the ease of access to evidence; (2) the cost for witnesses to attend trial; (3) the availability of compulsory process; and (4) other factors that might shorten trial or make it less

expensive. *Gilbert,* 330 U.S. at 508, 67 S. Ct. 839; *Piper Aircraft,* 454 U.S. at 241 n. 6, 102 S. Ct. 252.

Plaintiffs have demonstrated no meaningful ties to this district, the District of Connecticut or the United States. Instead, Plaintiffs argue that this Court should defer to their choice of forum because Pfizer performed research and development with respect to Trovan and made plans for the Nigerian experiment in Connecticut. However, such allegations do not affect Plaintiffs' ties to the state.[6] *Abdullahi I,* 2002 WL 31082956, at *10.

Because Plaintiffs assert claims under international law, any concerns regarding the difficulty in applying foreign law are not present here. Moreover, it is undeniable that Nigeria has a very strong interest in this litigation. The Trovan testing occurred in Nigeria and all the alleged victims are Nigerian. Further, Plaintiffs allege that Pfizer's experiment was made possible with the aid of several of Nigeria's own government officials. (Compl.¶ 6(h).) *See Abdullahi I,* 2002 WL 31082956, at *10-11; *see Piper Aircraft,* 454 U.S. at 260, 102 S. Ct. 252 (citing *Gilbert,*

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[6] Plaintiffs' choice of forum is not entitled to a greater deference because they have alleged international law violations. *See Aguinda v. Texaco, Inc.,* 142 F. Supp. 2d 534, 553 (S.D.N.Y. 2001) (even if the court assumed that Texaco participated in a violation of international law that would support the claim brought under the ATS, "neither that assumption nor any of the other considerations special to these cases materially alters the balance of private and public interest factors that, as previously discussed, 'tilt[s] strongly in favor of trial in the foreign forum.'" (citing *Wiwa,* 226 F.3d at 106) (internal citation omitted)).

330 U.S. at 509, 67 S. Ct. 839) (There is "a local interest in having localized controversies decided at home."). On the other hand, citizens of this district as well as the District of Connecticut share an interest in this litigation because Pfizer developed, produced and performed preliminary testing of Trovan and designed the Kano treatment protocol within the United States as part of its plan to obtain FDA approval to sell and distribute Trovan domestically. *See Carlenstolpe v. Merck & Co., Inc.*, 819 F.2d 33, 35 (2d Cir. 1987) (affirming a finding that there was a strong United States public interest in a products liability action concerning a vaccine that was developed in the United States but approved for distribution in Sweden). Thus, the *Gilbert* public interest factors do not strongly support either forum over the other. *Abdullahi I*, 2002 WL 31082956, at *11.

With regard to the *Gilbert* private interest factors, while discovery related to Pfizer's alleged tortious conduct must occur within the United States, Plaintiffs must establish proof of causation, injury and damages. *See Abdullahi I*, 2002 WL 31082956, at *11. Witnesses crucial to those factual inquiries-including the local hospital personnel who communicated with the Plaintiffs during the Trovan treatment, the Nigerian government officials who approved the study, the Kano IDH Ethics Committee and other Nigerian individuals with knowledge of the relevant events-are all located in Nigeria. Thus, evidence of numerous elements essential to Plaintiffs' claims is beyond Plaintiffs' control and, therefore, not amenable to discovery in this forum.

Further, most of the documents and witnesses located in the United States are within Pfizer's control. Pfizer has stipulated that it will facilitate any Nigerian action by providing Plaintiffs with relevant records; making past or present Pfizer employees available for depositions pursuant to 28 U.S.C. § 1782; and using its "best efforts" to make past and present employees of Pfizer who would be subject to subpoena in the Southern District of New York available to testify at trial in Kano at Pfizer's cost. (Pfizer's Memorandum in Support of its Motion to Dismiss, dated Sept. 19, 2005 at 15-16.) *See Abdullahi I*, 2002 WL 31082956, at *12; *Aguinda*, 142 F. Supp. 2d at 550 (defendant adequately addressed plaintiffs' concern for U.S. discovery through a stipulation). Thus, the balance of the *Gilbert* private interest factors clearly weighs in favor of granting Pfizer's motion to dismiss for *forum non conveniens*. *Abdullahi I*, 2002 WL 31082956, at *12.

## *CONCLUSION*

For the foregoing reasons, this Court grants Pfizer's motion to dismiss the Complaint for lack of subject matter jurisdiction under the Alien Tort Statute, Connecticut Unfair Trade Practices Act and the Connecticut Products Liability Act. Even if this Court had subject matter jurisdiction, it would dismiss the action on *forum non conveniens* grounds for the reasons stated in Part IV. This Court would condition dismissal on *forum non conveniens* grounds on the following grounds:

1. Defendant Pfizer consents to suit and acceptance of process in any suit Plaintiffs file in Nigeria on the claims that are the subject of the instant suit;

2. Defendant Pfizer waives any statute of limitations defense that may be available to it in Nigeria;

3. Defendant Pfizer makes available for discovery and for trial, at its own expense, any documents, or witnesses, including retired employees, within Pfizer's control that are needed for a fair adjudication of Plaintiffs' claims; and

4. Defendant Pfizer will not act to prevent Plaintiffs from returning to this Court if the Federal High Court in Nigeria declines to accept jurisdiction of this action, if it is filed in Nigeria within 60 days of the entry of this Order.

The Clerk of the Court is directed to mark this case closed.

SO ORDERED.

# APPENDIX E

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT
OF NEW YORK

Civil Action No. ___

## COMPLAINT AND JURY TRIAL DEMAND

Rabi Abdullahi, individually and as the natural guardian and personal representative of the estate of her daughter Lubabatu Abdullahi; Salisu Abullahi, individually and as the natural guardian and personal representative of the estate of his son Abdullahi (Manufi) Salisu; Abdullahi Alasan, individually and as the natural guardian and personal representative of the estate of his daughter Firdausi Abdullahi; Ali Hashirau, individually and as the natural guardian and personal representative of the estate of his daughter Suleiman Ali; Muhammadu Inuwa, individually and as the natural guardian and personal representative of the estate of his son Abdullahi M. Inuwa; Magaji Alh Ladan, individually and as the natural guardian and personal representative of the estate of his son Kabiru Isyaku; Alhaji Mustapha, individually and as the natural guardian and personal representative of the estate of his daughter Asma'u Mustapha; Suleiman Umar, individually and as the natural guardian and personal representative of the estate of his son Buhari Suleiman; Zainab Abdu, a minor, by her mother and natural guardian, Hajia Abdullahi, and Hajia Abdullahi individually; Firdausi Abdullahi, a minor, by her father and natural guardian, Abdullahi Madawaki, and

Abdullahi Madawaki individually; Sani Abdullahi, a minor, by his father and natural guardian, Abdullahi Madawaki, and Abdullahi Madawaki individually; Abdullahi Ado, a minor, by his mother and natural guardian, Aisha Ado, and Aisha Ado individually; Abdulmajid Ali, a minor, by his father and natural guardian, Alhaji Yusuf Ali, and Alhaji Yusuf Ali individually; Nura Muhammad Ali, a minor, by his father and natural guardian, Muhammad Ali, and Muhammad Ali individually; Umar Badamasi, a minor, by his father and natural guardian, Malam Badamasi Zubairu, and Malam Badamasi Zubairu indi-vidually; Muhammadu Fatahu Danladi, a minor, by his, father and natural guardian, Alhaji Danaldi Ibrahim, and Alhaji Danaldi Ibrahim individually; Dalha Hamza, a minor, by his father and natural guardian, Malam Hamza Gwammaja, and Malam Hamza Gwammaja individually; Tasiu Haruna, a minor, by his guardian Mukhtar Saleh, and Mukhtar Saleh individually; Muhyiddeen Hassan, a minor, by his father and natural guardian, Tijjani Hassan, and Tijjani Hassan individually; Kawu Adamu Ibrahim, a minor, by his father and natural guardian, Malam Abamus Ibrahim Adamu, and Malam Abamus Ibrahim Adamu individually; Sunusi Alh Ibrahim, a minor, by his father and natural guardian, Alhaji Ibrahim Hama, and Alhaji Ibrahim Haruna individually; Maryam Idris, a minor, by her father and natural guardian, Malam Idris, and Malam Idris individually; Yusif Idris, a minor, by his father and natural guardian, Idris Umar, and Idris Umar individually; Hafsat Isa, a minor, by her father and natural guardian, Isa Muhammed Isa, and Isa Muhammed Isa individually; Taju Isa, a minor, by

his father and natural guardian, Malam Isa Usman, and Malam Isa Usman individually; Hadiza Isyaku, a minor, by her father and natural guardian, Isyaku Shuaibu, and Isyaku Shuaibu individually; Zahra'u Jafaru, a minor, by her father and natural guardian, Jafaru Baba, and Jafaru Baba individually; Anas Mohammed, a minor, by his father and natural guardian, Malam Mohammed, and Malam Mohammed individually; Nafisatu Muhammed, a minor, by her mother and natural guardian, Yahawasu Muhammed, and Yahawasu Muhammed individually; and Muhsinu Tijjani, a minor, by his father and natural guardian, Tijjani Hassan, and Tijjani Hassan individually,

Plaintiffs,

v.

Pfizer, Inc.

Defendant.

Plaintiffs, by their attorneys, make the following allegations based upon information and belief pursuant to the investigation of counsel, except as to allegations specifically pertaining to themselves and their counsel, which are based on personal knowledge.

## I. SUMMARY OF ACTION

1. The minor plaintiffs in this action were the unwitting subjects of an experimental drug test conducted by Pfizer, Inc. ("Pfizer" or the "Company") in Kano, Nigeria. Pfizer never obtained informed consent from the minor plaintiffs or their parents. This test was conducted in violation of international laws and treaties, including the Nuremberg Code of

1947, which was enacted, in part, to prevent the horrors of medical experimentation performed during the Holocaust from ever happening again. The injuries suffered by the minor plaintiffs as a result of Pfizer's secret testing include, among other things, brain damage, loss of hearing, full loss of motor skills, and in some cases, the death of the children involved. Significantly, these children could have received an effective and proven alternative medication that was available and being dispensed to other sick children not chosen for Pfizer's test.

2. The genesis of the injuries and death that are the subject of the present action is defendant Pfizer's eagerness to benefit from an epidemic of bacterial meningitis in Nigeria. In the midst of the outbreak, Pfizer chartered a DC-9 airplane, and flew to Nigeria to conduct experiments on children who were in desperate need of medical care. Rather than provide the children with a safe, effective and proven therapy for bacterial meningitis, Pfizer chose to select children to participate in a medical experiment of a new, untested and unproven drug without first obtaining their informed consent, or explaining to the children or their parents that the proposed treatment was experimental, and that they were free to refuse it and instead choose the safe, effective treatment for bacterial meningitis being offered at the same site, free of charge, by a charitable medical group.

3. After the children were selected, they were taken from their parents and split into two groups. One half of the children selected were given Trovafloxacin Mesylate (which Pfizer branded "Trovan") -- an unproven drug to treat bacterial

meningitis, in a form never before tested on humans, for which the Company had completed insufficient animal testing, and which was known to have life-threatening side effects. The other half were purposefully "low-dosed" with an improperly administered control, ceftriaxone. The purposeful low dosing resulted in injuries and deaths among the control group as well, and therefore aided Pfizer in its claim that Trovan was efficacious, and perhaps more efficacious, than the other drugs on the market. In other clinical trials, Pfizer had been cited for "low-dosing" control drugs. Here, Pfizer's actions endangered and damaged these children's lives as the improper administration and dosage of ceftriaxone caused clinical failure, injuries and/or death.

4. Defendant Pfizer is the world's largest pharmaceutical company and a self-proclaimed "global leader in healthcare," which uses the advertising slogan "Committed to Kids" and states on its web site that "At Pfizer, we recognize that the first years of life are especially precious." The facts concerning Pfizer's conduct in the Kano drug experiment stand in stark contrast to that advertising campaign.

5. When Pfizer went to Kano to carry out the experiment (hereinafter the "Kano Trovan Test"), this impoverished and strife-torn city in Northern Nigeria was experiencing concurrent epidemics of bacterial meningitis, measles, and cholera. But rather than making the trip to provide humanitarian relief, as charitable organizations were doing, Pfizer hurried to Kano to exploit the misfortune there for its own benefit, and in fact undermined the highly

successful humanitarian efforts being taken by others, including Medecins Sans Frontieres ("MSF"), the Nobel Prize-winning humanitarian relief organization also known as Doctors Without Borders.

6. Pfizer took the opportunity presented by the chaos caused by the civil and medical crises in Kano to accomplish what the Company could not do elsewhere -- to quickly conduct on young children a test of the potentially dangerous antibiotic Trovan. As a result, numerous children were prevented from receiving adequate medical care, and were injured, maimed or died.

7. Pfizer expected to realize substantial financial benefits for itself from the trial. If Pfizer obtained FDA approval for Trovan's use for pediatric victims of bacterial meningitis, American pediatricians would be free to prescribe the drug for any use, opening up a lucrative market for the Company. Further, if Pfizer was able to secure broad FDA approval for Trovan, the Company could generate billions of dollars in corporate revenue.

8. Pfizer hastily cobbled together a protocol in a period of mere weeks. Then, in March of 1996, a Pfizer research team installed itself for a month-long stay at Kano's Infectious Disease Hospital. There, the Company's representatives selected children it deemed suitable for its test from the long lines of ailing people seeking care at this unsanitary and rudimentary hospital.

9. In its zeal to carry out its risky test, Pfizer took a variety of steps which violated international law, federal regulations and principles of medical ethics. Indeed, years later, Pfizer

fraudulently back-dated necessary approvals in an attempt to at least partially cover its tracks.

10. Foremost among Pfizer's violations was its failure to get any consent, informed or otherwise, before performing medical experiments on the subject children, in contravention of customary international law and as specifically forbidden by the Nuremberg Code, the Declaration of Helsinki, and the International Covenant on Civil and Political Rights (the "ICCPR"). In fact, the families involved understood that Pfizer was providing their children with volunteer relief, not that their children were "being volunteered" to help Pfizer.

11. Pfizer further violated customary international law by failing to inform the families that there was an alternative to the "treatment" being provided by Pfizer. Specifically, MSF had set up a tent on the IDH grounds where a team of its medical personnel with training and experience in epidemic relief work was treating its pediatric meningitis patients with Chloramphenicol, the internationally recommended treatment for bacterial meningitis.

12. Among other violations of customary international law, Pfizer: (i) failed to develop and adhere to an appropriate test protocol; (ii) failed to perform necessary diagnostic and evaluative testing to ensure that the children selected for its Kano Trovan Test did in fact suffer from bacterial meningitis; (iii) failed to ensure that the test site had sufficient medical staff; necessary materials and sanitation to safely and properly carry out the test; (iv) failed to modify treatment for those children who did not improve after the initial course of therapy;

and (v) failed to conduct any, let alone appropriate, follow-up treatment to determine what impact the Kano Trovan Test had on its participants.

13. At the time the test was carried out, Pfizer was aware of the serious flaws in the Kano Trovan Test and the illegality of its actions. A Pfizer infectious disease specialist assigned to the Kano Trovan Test repeatedly informed Pfizer senior management (before, during, and after the execution of the Test) that the Kano Trovan Test violated international law, federal regulations and medical ethical standards.

14. Pfizer's violation of international law and federal regulations in the Kano Trovan Test had significant and devastating consequences for the plaintiffs. Several children died shortly after participating in the Kano Trovan Test. Others have suffered permanent physical and/or neurological damages, including paralysis, deafness, and brain damage.

15. Plaintiffs bring this action pursuant to the Alien Tort Claims Act to recover damages against Pfizer flowing from Pfizer's violations of international law, as set forth, inter alia, in the Nuremberg Code, the Declaration of Helsinki, article 7 of the ICCPR, and other norms of international law proscribing medical experimentation on humans without their consent, and prohibiting torture or other cruel, inhuman, or degrading treatment or punishment.

## II. PARTIES

16. Rabi Abdullahi, who resides at Kwanar Jajira Bachirawa, was the mother and natural

guardian of the late Lubabatu Abdullahi, a girl who died at the age of 13 shortly after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Rabi Abdullahi brings this Action on behalf of her late daughter's estate and on her own behalf individually.

17. Salisu Abdullahi, who resides at No. 16 Madigawa, Dala L.G., was the father and natural guardian of the late Abdullahi (Manufi) Salisu, a boy who died at the age of 2 after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Salisu Abdullahi brings this Action on behalf of his late son's estate and on his own behalf individually.

18. Abdullahi Alasan, who resides at No. 260 Bachirawa Quarters, was the father and natural guardian of Firdausi Abdullahi, a girl who died at the age of 16 months after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Abdullahi Alasan brings this Action on behalf of his late daughter's estate and on his own behalf individually.

19. Ali Hashimu, who resides at Unguwa Uku, Tarauni, Kano, Nigeria, was the father of the late Suleiman Ali, a girl who died at the age of 4 shortly after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Ali Hashimu brings this Action on behalf of his late daughter's estate and on his own behalf individually.

20. Muhammadu Inuwa, who resides at Kwanar Jajira, Bachirawa, was the father and natural guardian of the late Abdullahi M. Inuwa, a boy who died at the age of 2 shortly after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Muhammadu Inuwa brings this Action on behalf of his late son's estate and on his own behalf individually.

21. Magaji Alh Ladan, who resides at Danrimi, Ungogo L.G., was the father and natural guardian of the late Kabiru Isyaku, a boy who died at the age of 4 shortly after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Magaji Alh Ladan brings this Action on behalf of his late son's estate and on his own behalf individually.

22. Suleiman Umar, who resides at Rimin Kebe, Ungogo, Kano, Nigeria, was the father of the late Buhari Suleiman, a boy who died at the age of 3 shortly after being subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria. Suleiman Umar brings this Action on behalf of his late son's estate and on his own behalf individually.

23. Zainab Abdu is a now 16 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Zainab Abdu was left deaf and mute. Hajia Abdullahi, who resides at Madigawa, Dala L.G., is the mother and natural guardian of Zainab Abdu,

and brings this Action on her behalf and on her own behalf individually.

24. Firdausi Abdullahi is a now 6 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Firdausi Abdullahi was left brain damaged, deaf and mute. Abdullahi Madawaki, who resides at Kwachiri Kurnar Asabe Fagge, Kano, Nigeria, is the father and natural guardian of Firdausi Abdullahi, and brings this Action on her behalf and on his own behalf individually.

25. Abdullahi Ado is a now 10 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Abdullahi Ado was left deaf and mute. Aisha Ado, who resides at Bacharawa Quarters, Ungogo, Kano, Nigeria, is the mother and natural guardian of Abdullahi Ado, and brings this action on his behalf and on her own behalf individually.

26. Sani Abdullahi is a now 11 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Sani Abdullahi was left with paralysis of his right arm and leg. Abdullahi Madawaki, who resides at Kwachiri Kumar Asabe Fagge, Kano, Nigeria, is the father and natural guardian of Sani Abdullahi, and brings this Action on his behalf and on his own behalf individually.

27. Abdulmajid Ali is a now 8 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Abdulmajid was left partially paralyzed. Alh. Yusuf Ali, who resides at 289 Kul-Kul, Dala L.G.A., is the father and natural guardian of Abdulmajid Ali, and brings this Action on his behalf and on his own behalf individually.

28. Nura Muhammad Ali is a now 12 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. Muhammad Ali, who resides at Yammata-Tsamiyar Zubai, Bachirawa, is the father and natural guardian of Nura Muhammad Ali, and brings this Action on his behalf and on his own behalf individually.

29. Umar Badamasi is a now 9 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Umar Badamasi was left partially paralyzed. Malam Badamasi Zubairu, who resides at Kurna-Makaranta, Fagge L-GA, is the father and natural guardian of Umar Badamasi, and brings this Action on his behalf and on his own behalf individually.

30. Muhammadu Fatahu Danladi is a now 13 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. Alhaji Danladi Ibrahim,

who resides at No. 118 Sanka Quarters, Dala L.G. is the father, and natural guardian of Muhammadu Fatahu Danladi, and brings this Action on his behalf and on his own behalf individually.

31. Dalha Hamza is a now 12 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Dalha Hamza was left deaf and mute. Malam Hamza Gwammaja, who resides at Lain Shehu Mai Haisi, Gwammaja, Dala L.G., is the father and natural guardian of Dalha Hamza, and brings this Action on his behalf and on his own behalf individually.

32. Tasiu Haruna is a now 9 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Tasiu Haruna was left deaf and mute. Mukhtar Saleh, the village head, or chief of Gayama Village, Ungogo, Kano, Nigeria, is empowered to be the natural guardian of Tasiu Haruna, and brings this Action on his behalf and on his own behalf individually.

33. Muhyiddeen Hassan is a now 7 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Muhyiddeen was left deaf and mute. Tijjani Hassan, who resides at Dandali Kul-Kul, Dala L.G., is the father and natural guardian of Muhyiddeen

Hassan, and brings this Action on his behalf and on his own behalf individually.

34. Kawu Adamu Ibrahim is a now 14 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kane Trovan Test, Kawu Adamu Ibrahim was left mute. Malam Abamus Ibrahim Adamu, who resides at Dan-Rimi, Ungogo L.G., is the father and natural guardian of Kawu Adamu Ibrahim, and brings this Action on his behalf and on his own behalf individually.

35. Sunusi Alh. Ibrahim is a now 14 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Sunusi Alh. Ibrahim was left partially paralyzed and blind. Alhaji Ibrahim Haruna, who resides at Danrimi, Ungogo L.G., is the father and natural guardian of Sunusi Alh. Ibrahim, and brings this Action on his behalf and on his own behalf individually.

36. Maryam Idris is a now 9 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Maryam Idris was left deaf, mute, and partially paralyzed. Malam Idris, who resides at Kwanar Jajira, Bachirawa, is the father and natural guardian of Maryam Idris, and brings this Action on her behalf and on his own behalf individually.

37. Yusif Idris is a now 6 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Yusif Idris was left deaf and mute. Idris Umar, who resides at Mile 9 Kadawa Ungogo, Kano, Nigeria, is the father and natural guardian of Yusif Idris, and brings this Action on his behalf and on his own behalf individually.

38. Hafsat Isa is a now 9 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Hafsat Isa was left partially paralyzed and suffering from seizures. Isa Muhammed Isa, who resides at No. 244A Kwachiri Kumar Asabe, Fagge, Kano, Nigeria, is the father and natural guardian of Hafsat Isa, and brings this Action on her behalf and on his own behalf individually.

39. Taju Isa is a now 6 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Taju Isa was left deaf and mute. Malam Isa Usman, who resides at Dogon Nama, Dala L-GA, is the father and natural guardian of Taju Isa, and brings this Action on his behalf and on his own behalf individually.

40. Hadiza Isyaku is a now 7 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH

Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Hadiza Isyaku was left brain damaged. Isyaku Shuaibu, who resides at Bacharawa Quarters, Ungogo, Kano, Nigeria, is the father and natural guardian of Hadiza Isyaku, and brings this Action on her behalf and on his own behalf individually.

41. Zahra'u Jafaru is a now 6 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Zahra'u Jafaru was left deaf and mute. Jafaru Baba, who resides at No. 360 Yelwa Quarters, Durumin Kul-Kul, Dala L.G., Kano, Nigeria is the father and natural guardian of Zahra'u Jafaru, and brings this Action on her behalf and on his own behalf individually.

42. Anas Mohammed is a now 12 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Anas Mohammed was left with partial paralysis. Malam Mohammed, who resides at Yammata, Dala L.G., is the father and natural guardian of Anas Mohammed, and brings this Action on his behalf and on his own behalf individually.

43. Nafisatu Muhammed is a now 8 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Nafisatu Muhammed was left deaf and

mute. Yahawasu Muhammed, who resides at Bacharawa Quarters, Ungogo, Kano, Nigeria, is the mother and natural guardian of Nafisatu Muhammed, and brings this Action on her behalf and on her own behalf individually.

44. Asma'u Mustapha is a now 10 year-old girl who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. Alhaji Mustapha, who resides at Kul-Kul, Dala L.G. Kano, Nigeria, is the father and natural guardian of Asma'u Mustapha, and brings this action on her behalf and on his own behalf individually.

45. Muhsinu Tijjani is a now 9 year-old boy who was subjected by Pfizer to the Kano Trovan Test administered in March and April 1996 at the IDH Hospital in Kano, Nigeria, and suffered injuries as a result. After participating in the Kano Trovan Test, Muhsinu Tijjani was left partially paralyzed. Tijjani Hassan, who resides at Dandali Kul-Kul, Dala L.G., is the father and natural guardian of Muhsinu Tijjani, a minor, and brings this Action on his behalf and on his own behalf individually.

46. Defendant Pfizer is a Delaware corporation which maintains its world headquarters at 235 East 42nd Street, New York, New York 10017. At all times relevant hereto, Pfizer was engaged in the business of developing and manufacturing the pharmaceutical product Trovan.

## III. JURISDICTION

47. This Court has jurisdiction pursuant to 28 U.S.C. § 1332. The plaintiffs are all citizens or subjects of a foreign state (Nigeria), the defendant is

a citizen of a U.S. State, and the amount in controversy exceeds $75,000.

48. This Court also has jurisdiction pursuant to 28 U.S.C. § 1331, which confers district courts with original jurisdiction over all civil actions arising under the laws, including customary international law, and treaties of the United States.

49. This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1350, the Alien Tort Claims Act, which provides that " [t]he district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."

50. The Alien Tort Claims Act permits aliens to bring actions against non-state actors for tort claims arising from violations of customary international law. See *Kadic v. Karadzic*, 70 F.3d 232, 239 (2d Cir. 1995).

## IV. LEGAL FRAMEWORK

### A. Relevant Customary International Law and Treaties of the United States

51. Customary international law is made up of the fundamental principles of a civilized society that are so widely held that they constitute binding norms on the community of nations. The Restatements of the Law, Third, Foreign Relations Law, § 102 (1987), defines customary international law as "general principles common to the major legal systems of the world" and as the "general and

consistent practice of states followed by them from a sense of legal obligation."

52. The law of nations, which has always been part of the federal common law "may be ascertained by consulting the works of jurists, writing professedly on public law; or by the general usage and practice of nations; or by judicial decisions recognizing and enforcing that law."[1]

53. The general usage and practice of nations in the field of human rights may be found in treaties, internationally or regionally adopted covenants, declarations of human rights, and the foreign policy goals of the United States and other countries in the field of human rights.[2]

54. American Courts have recognized that the right to be free from cruel, unhuman or degrading treatment is a universally accepted customary human rights norm.[3]

55. Furthermore, it is generally conceded that the core of customary international law are the

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[1] *United States v. Smith*, 18 U.S. 153, 160-61 (1820).

[2] *See Jama v. United States Immigration and Naturalization Serv.*, 22 F. Supp. 2d 353, 361 (D.N.J. 1998).

[3] *See, e.g., Filartiga v. Pena-Irala*, 630 F.2d 876, 880, 884-86 (2d Cir. 1980) (torture perpetrated under the color of official authority violates universally accepted norms of international human rights law, and such a violation of international law constitutes a violation of the domestic law of the United States, giving rise to a claim under the ATCA).

requirements of minimal decency articulated by the Nuremberg Code. The Nuremberg Code sets forth the international standards of conduct governing biomedical research on human subjects and was drafted in response to the horrors of the Nazi's depraved medical experimentation on children as well as adults.

56. The Nuremberg Code of 1947 states:

> Principle 1:
>
> ***The voluntary consent of the human subject is absolutely essential.***
>
> ***This means that the person involved should have legal capacity to give consent;*** should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and ***should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards***

***reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.***

***The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.***

Principle 2

The experiment should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature.

Principle 3

***The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.***

Principle 4

The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

Principle 5

***No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur;*** except, perhaps, in those experiments where the experimental physicians also serve as subjects.

Principle 6

The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

Principle 7

***Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability or death.***

Principle 8

The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

Principle 9

***During the course of the experiment the human subject should be at liberty to bring the experiment to an***

> ***end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.***
>
> Principle 10
>
> ***During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.***

(emphasis added).

57. The Nuremberg Code has become a part of the law of nations, and the international common law, and can be applied to both civil and criminal cases in state and federal courts in the United States.

58. The Nuremberg Code's proscription of biomedical research without informed consent is also enshrined in the ICCPR, a treaty to which the United States is a party. The ICCPR provides in article 7 that,

> No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. ***In particular, no one shall be subjected***

> ***without his free consent to medical or scientific experimentation***.

(emphasis added).

59. The ICCPR was adopted and opened for signature, ratification and accession by the U.N. General Assembly in 1966 and entered into force in 1976. Thus, medical experimentation without informed consent is a violation of article 7 of the ICCPR and therefore a violation of international law.

60. As the Office of the United Nations High Commissioner for Human Rights general commentary to article 7 explains,

> the prohibition in article 7 relates not only to acts that cause physical pain but also to acts that cause mental suffering to the victim. . . it is appropriate to emphasize in this regard that ***article 7 protects, in particular, children,*** pupils and ***patients in teaching and medical institutions. . . . The right to lodge complaints against maltreatment prohibited by article 7 must be recognized in the domestic law***.

October 4, 1992 ICCPR General comment 20 (emphasis added).

61. More generally, the Universal Declaration of Human Rights at article 5 states, "No one shall be subject to torture or to cruel, inhuman or degrading treatment or punishment."

62. The Declaration of Helsinki of the World Medical Association, first promulgated in 1964

(the "Declaration"), also prohibits non-consensual medical experimentation. The Declaration has been called the fundamental document in the field of ethics in biomedical research.

63. The Declaration sets forth minimum acceptable international standards for the conduct of medical experimentation on humans. The Declaration provides, among other things, that:

> Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
>
> The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance.
>
> Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. . . .
>
> Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject. . . .

Concern for the interests of the subject must always prevail over the interests of science and society.

***The right of the research subject to safeguard his or her integrity must always be respected . . .***

Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. . . .

***In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail . . . .***

***The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.***

***In any medical study, every patient - including those of a control group, if any - should be assured of the best proven diagnostic and therapeutic method.***

The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its

> potential diagnostic or therapeutic value for the patient.

(Emphasis added).

64. Another source of international standards for medical research is International Ethical Guidelines for Research Involving Human Subjects (the "CIOMS Guidelines") jointly produced by the Council for International Organizations of Medical Sciences ("CIOMS") and the World Health Organization. The CIOMS Guidelines were created to provide guidance as to how the ethical principles embodied in the Nuremberg Code, article 7 of the ICCPR, and the Declaration of Helsinki could be effectively applied in developing countries. These guidelines emphasize the importance of informed consent and establish principles for doing research in "underdeveloped communities" and further evidence international agreement on guiding principles for medical research involving human subjects.

65. The CIOMS Guidelines state in relevant part:

> ***Guideline 1: Individual Informed Consent***
>
> **For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorized representative.**

*Commentary on Guideline 1*

*General considerations.* Informed consent is consent given by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.

Informed consent is based on the principle that competent individuals are entitled to choose freely whether to participate in research.

In itself, informed consent is an imperfect safeguard for the individual, and it must always be complemented by independent ethical review of research proposals. Moreover, many individuals, including young children, many adults with severe mental or behaviourial disorders, and many persons who are totally unfamiliar with modem medical concepts, are limited in their capacity to give adequate informed consent. Because their consent could imply passive and uncomprehending participation, investigators must on no account presume that consent given by such vulnerable individuals is valid, without the prior approval of an independent ethical-review body. When an individual is incapable of making an

informed decision whether to participate in research, the investigator must obtain the proxy consent of the individual's legal guardian or other authorized representative.

Investigators should never initiate research involving-human subjects without obtaining each subject's informed consent, unless they have received explicit approval to do so from an ethical review committee.

***Guideline 2: Essential information for prospective research subjects***

**Before requesting an individual's consent to participate in research, the investigator must provide the individual with the following information, in language that he or she is capable of understanding:**

- **that each individual is invited to participate as a subject in research, and the aims and methods of the research; - the expected duration of the subject's participation; -the benefits that might reasonably be expected to result to the subject or to others as an outcome of the research;**
- **any foreseeable risks or discomfort to the subject**

associated with participation in the research;

- any alternative procedures or courses of treatment that might be as advantageous to the subject as the procedure or treatment being tested;
- the extent to which confidentiality of records in which the subject is identified will be maintained;
- the extent of the investigator's responsibility, if any, to provide medical services to the subject;
- that therapy will be provided free of charge for specified types of research-related injury;
- whether the subject or the subject's family or dependants will be compensated for disability or death resulting from such injury; and
- that the individual is free to refuse to participate and will be free to withdraw from the research at any time without penalty or loss of benefits to which he or she would otherwise be entitled.

*Commentary on Guideline 2*

*Risks.* In the case of complex research projects it may be neither feasible nor desirable to inform prospective subjects fully about every possible risk. *However, they must be informed of all risks that a reasonable person would consider material to making a decision about whether to participate.* An investigator's judgment about what risks are to be considered material should be reviewed and approved by the ethical review committee (see Guideline 3). Subjects who desire additional information should be afforded an opportunity to ask questions. (emphasis added).

* * *

***Guideline* 3: Obligations of investigators regarding informed consent**

**The investigator has a duty to:**

- **communicate to the prospective subject all the information necessary for adequately informed consent;**
- **give the prospective subject full opportunity and encouragement to ask questions;**
- **exclude the possibility of unjustified deception, undue influence and intimidation;**

- **seek consent only after the prospective subject has adequate knowledge of the relevant facts and of the consequences of participation, and has had sufficient opportunity to consider whether to participate;**
- **as a general rule, obtain from each prospective subject a signed form as evidence of informed consent; and**
- **renew the informed consent of each subject if there are material changes in the conditions or procedures of the research.**

*Commentary on Guideline 3*

*Necessary information.* The standards for communicating information as set forth in Guidelines 2 and 3 should be regarded as minimum. Other types of information that should be conveyed include the reasons for selecting prospective subjects (ordinarily because they either have certain diseases or have no apparent disease) and certain features of the research design (for example, randomization, double-blind, case-control), stated in language that the subjects can understand. . . . . In general the standard for communicating

information is that any and all information that a reasonable person would consider material to reaching a decision about whether to consent should be communicated.

* * *

*Undue influence.* The investigator should not give the prospective subject any unjustifiable assurances about the benefits, risks or inconveniences of the research.

* * *

*Intimidation.* Prospective subjects who are patients often depend upon the investigator for medical care, and the investigator has a certain credibility in their eyes. . . . The investigator must assure prospective subjects that their decision on whether to participate will not affect the therapeutic relationship or any other benefits to which they are entitled.

*Documentation of consent.* Consent may be indicated in a number of ways. The subject may imply consent by his or her voluntary actions, express consent orally, or sign a consent form. As a general rule, the subject should sign a consent form, or, in the case of incompetence, a legal guardian or other duly authorized representative should do so. The ethical review committee may approve the waiving of the

requirement of a signed consent form if the research carries no more than minimal risk and if the procedures to be used are only those for which signed consent forms are not customarily required outside the research context. ... [T]hese may resemble consent forms in all respects except that subjects are not required to sign them.

* * *

***Guideline 5: Research involving children***

**Before undertaking research involving children, the investigator must ensure that:**

* * *

- **a parent or legal guardian of each child has given proxy consent;**
- **the consent of each child has been obtained to the extent of the child's capabilities;**
- **the risk presented by interventions not intended to benefit the individual child-subject is low and commensurate with the importance of the knowledge to be gained; and**
- **interventions that are intended to provide therapeutic benefit are likely**

**to be at least as advantageous to the individual child-subject as any available alternative.**

*Commentary on Guideline 5*

* * *

*Consent of the child . . . . Older children who are capable of informed consent should be selected before younger children or infants, unless there are important scientific reasons related to age for involving younger children first. (emphasis added).*

* * *

*Proxy consent of a parent or guardian.* The investigator must obtain the proxy consent of the parent or guardian in accordance with local laws or established procedures.

* * *

*Observation of research by parent.* A parent or guardian who gives proxy consent for a child to participate in research should be given the opportunity to observe the research as it proceeds, so as to be able to withdraw the child from the research if the parent or guardian decides it is in the child's best interests to do so.

* * *

***Guideline 8: Research involving subjects in underdeveloped communities***

**Before undertaking research involving subjects in underdeveloped communities, whether in developed or developing countries, the investigator must ensure that:**

- **persons in underdeveloped communities will not ordinarily be involved in research that could be carried out reasonably well in developed communities;**
- **the research is responsive to the health needs and the priorities of the community in which it is to be carried out;**
- **every effort will be made to secure the ethical imperative that the consent of individual subjects be informed; and**
- **the proposals for the research have been reviewed and approved by an ethical review committee that has among its members or consultants persons who are thoroughly familiar with the customs and traditions of the community.**

*Commentary on Guideline 8*

* * *

Individuals and families in such communities are liable to exploitation for various reasons. Some of them may be relatively incapable of informed consent because they are illiterate, unfamiliar with the concepts of medicine held by the investigators, or living in communities in which the procedures typical of informed-consent discussions are unfamiliar or alien to the ethos of the community. Certain investigators may wish to take advantage of the lack in most developing countries of well-developed regulations or ethical review committees, which could have the effect of delaying access to research subjects; others may find it less expensive to conduct in developing countries research designed to develop drugs and other products for the markets of developed countries.

* * *

Investigators must respect the ethical standards of their own countries and the cultural expectations of the societies in which research is undertaken, unless this implies a violation of a transcending moral role.

* * *

The research conducted in underdeveloped communities should be responsive to the health needs and priorities of those communities. It should not exhaust resources which the community usually devotes to the health care of its members. If any product is to be developed, such as a new therapeutic agent, clear understanding should be reached among investigators, sponsors, representatives of the collaborating countries, and community leaders about what the community is to expect and what can or cannot be provided during and at the close of the research. Such understanding must be reached before the research is begun, to ensure that the research is truly responsive to the priorities of the community.

* * *

*Informed consent.* All reasonable efforts should be made to obtain the informed consent of each prospective subject according to the standards specified in Guidelines 1 to 3, to ensure that the rights of prospective subjects are respected. For example, when because of communication difficulties investigators cannot make prospective subjects sufficiently aware of the implications of participation to give adequately informed consent, the decision of each prospective subject on

whether to consent should be elicited through a reliable intermediary such as a trusted community leader. . . . However consent is obtained, all prospective subjects must be clearly told that their participation is entirely voluntary, and that they are free to refuse to participate or to withdraw their participation at any time without loss of any entitlement. The investigator is required to ensure that each prospective subject is clearly told everything that would be conveyed if the study were to be conducted in a developed community and, further, to ensure that earnest attempts are made to enable the prospective subject to understand this information; otherwise, assurance of freedom to refuse or withdraw from participation would be meaningless.

All plans to use the above standard for informing, providing assistance with understanding, and assuring freedom to refuse or withdraw must be approved by an ethical review committee and supplemented with other means of assuring that the rights of prospective subjects are respected.

*Ethical review.* The ability to judge the ethical acceptability of various aspects of a research proposal requires a thorough understanding of a community's customs and traditions.

The ethical review committee must have as either members or consultants persons with such understanding, so that the committee may evaluate proposed means of obtaining informed consent and otherwise respecting the rights of prospective subjects. Such persons should be able, for example, to identify appropriate members of the community to serve as intermediaries between investigators and subjects, to decide whether material benefits or inducements may be regarded as appropriate in the light of a community's gift-exchange traditions, and to provide safeguards for data and personal information that subjects consider to be private or sensitive.

* * *

***Guideline 10: Equitable distribution of burdens and benefits***

**Individuals or communities to be invited to be subjects of research should be selected in such a way that the burdens and benefits of the research will be equitably distributed. Special justification is required for inviting vulnerable individuals and, if they are selected, the means of protecting their rights and welfare must be particularly strictly applied.**

*Commentary on Guideline 10*

*General considerations.* . . . Classes of individuals traditionally considered vulnerable are those with limited capacity or freedom to consent. They are the subject of specific guidelines in this publication and include children. Ethical justification of their involvement usually requires that investigators satisfy ethical review committees that:

- the research could not be carried out reasonably well with less vulnerable subjects;
- the research is intended to obtain knowledge that will lead to improved diagnosis, prevention or treatment of diseases or other health problems characteristic of or unique to the vulnerable class, either the actual subjects or other similarly situated members of the vulnerable class;
- research subjects and other members of the vulnerable class from which subjects are recruited will ordinarily be assured reasonable access to any diagnostic, preventive or therapeutic products that will become available as a consequence of the research;

- the risks attached to research that is not intended to benefit individual subjects will be minimal, unless an ethical review committee authorizes a slight increase above minimal risk (see Guideline 5); and
- when the prospective subjects are either incompetent or otherwise substantially unable to give informed consent, their agreement will be supplemented by the proxy consent of their legal guardians or other duly authorized representatives.

* * *

***Guideline 13: Right of subjects to compensation***

**Research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death, their dependants are entitled to material compensation. The right to compensation may not be waived.**

*Commentary on Guideline 13*

* * *

*Obligation of the sponsor to pay.* The sponsor, whether a pharmaceutical company, a government, or an institution, should agree, before the research begins, to provide compensation for any physical injury for which subjects are entitled to compensation. Sponsors are advised to obtain adequate insurance against risks to cover compensation, independent of proof of fault.

***Guideline 14: Constitution and responsibilities of ethical review committees***

**All proposals to conduct research involving human subjects must be submitted for review and approval to one or more independent ethical and scientific review committees. The investigator must obtain such approval of the proposal to conduct research before the research is begun.**

*Commentary on Guideline 14*

*General considerations.* Whatever the circumstances, however, society has a dual responsibility to ensure that:

- all drugs, devices and vaccines under investigation in human

subjects meet adequate standards of safety; and

- the provisions of the Declaration of Helsinki are applied in all biomedical research involving human subjects.

*Assessment of safety.* Authority to assess the safety and quality of medicines and vaccines intended for use in humans is most effectively vested in a multidisciplinary advisory committee.

* * *

Committees competent to review and approve scientific aspects of clinical trials must be multidisciplinary, much like those specified earlier for assessment of safety. In many cases such committees operate most effectively at the national level.

* * *

In Phases II and III of drug testing and Phase III of vaccine testing, when benefits are intended for the subjects and they are reasonably likely to be realized, it is permissible to involve members of vulnerable groups and persons with limited capacity to consent. However, as required by the Declaration of Helsinki, Article II.3, "every patient -- including those of a control group, if any -- should be

assured of the best proven diagnostic and therapeutic method."

* * *

Ethical justification to begin a randomized clinical trial also meets the requirements of Article II.3. The therapies (or other interventions) to be compared must be regarded as equally advantageous to the prospective subjects: there should be no scientific evidence to establish the superiority of one over another. Moreover, no other intervention must be known to be superior to those being compared in the clinical trial, unless eligibility to participate is limited to persons who have been unsuccessfully treated with the other superior intervention or to persons who are aware of the other intervention and its superiority and have chosen not to accept it.

For each randomized clinical trial there should be a data and safety monitoring committee, responsible for monitoring the data obtained in the course of a study and for making recommendations to the sponsors and investigators about modifying or terminating the study, or about amending the informed-consent process or form.

* * *

*Committee membership.* Local review committees should be so composed as to

be able to provide complete and adequate review of the research activities referred to them. They should include physicians, scientists and other professionals, such as nurses, lawyers, ethicists and clergy, as well as lay persons qualified to represent the cultural and moral values of the community. The membership should include both men and women.

* * *

Similarly, committees that review research involving such vulnerable groups as children, students, aged persons or employees should consider the advantages of including representatives of or advocates for, such groups.

* * *

*Need for particularly stringent review requirements.* The requirements of review committees should be particularly stringent in the case of proposed research involving children, ... communities unfamiliar with modem clinical concepts. ... In considering such proposals the review committee should be especially attentive in determining that selection of research subjects is both equitable (designed to distribute fairly the burdens and benefits of research) and likely to minimize risk to subjects.

* * *

*Information to be provided by investigators.* Whatever the procedure adopted for ethical review, such review should be based on a detailed protocol comprising:

- a clear statement of the research objectives, having regard to the present state of knowledge, and a justification for undertaking the investigation in human subjects;
- a precise description of all proposed interventions, including intended dosages of drugs and planned duration of treatment;
- a description of plans to withdraw or withhold standard therapies in the course of the research;
- a description of the plans for statistical analysis of the study, which includes a calculation of the statistical power of the study, specifies the criteria for terminating the study, and demonstrates that the proper number of subjects will be recruited;
- the criteria determining admission and withdrawal of individual subjects, including full details of the procedure for

seeking and obtaining informed consent;

- an account of any economic or other inducements to participate, such as offers of cash payments, gifts, or free services or facilities, and of any financial obligations assumed by the subjects, such as payment for medical services; and
- for research carrying more than minimal risk of physical injury, an account of plans, if any, to provide medical therapy for such injury and to provide compensation for research-related disability or death.

Information should also be included to establish:

- the safety of each proposed intervention and of any drug or vaccine to be tested, including the results of relevant laboratory and animal research;
- the anticipated benefits and the risks of participation;
- the means proposed to obtain individual informed consent or, when a prospective subject is not capable of informed consent, satisfactory assurance that proxy consent will be obtained from a duly authorized person and that

the rights and welfare of each subject will be adequately protected;

- the identification of the organization that is sponsoring the research and a detailed account of the sponsor's financial commitments to the research institution, investigators, research subjects and, when appropriate, the community;
- plans to inform subjects about harms and benefits during the study, and of the results of the study at its conclusion;
- an explanation of who will be involved in the research, their age, sex and circumstances, and, if any classes are excluded, the justification for the exclusion;
- justification for involving as research subjects persons with limited capacity to consent or members of vulnerable social groups;
- evidence that the investigator is qualified and experienced and is assured of adequate facilities for the safe and efficient conduct of the research;

- provisions that will be made for protecting the confidentiality of data; and,
- the nature of any other ethical considerations involved, together with an indication that the principles of the Declaration of Helsinki will be implemented.

***Guideline 15: Obligations of sponsoring and host countries***

**Externally sponsored research entails two ethical obligations:**

- **An external sponsoring agency should submit the research protocol to ethical and scientific review according to the standards of the country of the sponsoring agency, and the ethical standards applied should be no less exacting than they would be in the case of research carried out in that country.**
- **After scientific and ethical approval in the country of the sponsoring agency, the appropriate authorities of the host country, including a national or local ethical review committee or its equivalent, should satisfy themselves that the proposed**

> **research meets their own ethical requirements.**
>
> *Commentary on Guideline 15*
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> * * *
>
> *Obligations of external sponsors* ... [S]ponsors have an obligation to ensure that subjects who suffer injury... as a consequence of research interventions obtain medical treatment free of charge, and that compensation is provided for death or disability occurring as a consequence of such injury. Sponsors are expected to ensure that research subjects and the communities for which they are recruited are not made worse off as a result of the research (apart from justifiable risks of research interventions) for example, by the diversion of scarce local resources to research activities.

**B. <u>Specific Provisions Guaranteeing a Private Remedy for Human Rights Abuses</u>**

66. The ICCPR requires each state party to ensure victims of abuses "an effective remedy." ICCPR art. 2(3)(a).

67. The United Nations Universal Declaration of Human Rights states at Article 8, "Everyone has the right to an effective remedy by the competent national tribunals for acts violating [one's] fundamental rights". The remedy must be adjudicatory, guaranteeing the victim of a human

rights abuse his or her day in court." Universal Declaration of Human Rights, G.A. res. 217A (III) (Dec. 10, 1948); U.N. GAOR, 3d Sess. Supp. No. 49.

### C. Relevant United States Regulations Concerning Human Experimentation

68. The FDA may accept clinical studies conducted outside the U.S. in support of safety and efficacy claims for drugs, but these studies, generally conducted under an Investigational New Drug ("IND") exemption, are governed by the FDA informed consent and Institutional Review Board ("IRB") requirements.[4] [See 21 C.F.R. § 312 (2001), IND Regulations].

69. The FDA will accept a foreign clinical study involving a drug not conducted under an IND only if the study conforms to whichever of the following provides greater protection of human subjects: the ethical principles contained in the 1989 version of the Declaration of Helsinki (which as discussed above, among other things, requires that informed consent be obtained) or the laws and

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[4] IRBs are responsible for continuing review of ongoing research to ensure that the rights and welfare of human subjects are protected. IRBs are designed to function as independent peer review for clinical research. IRBs are required to approve research. Among other responsibilities, the IRB should ensure that risks to subjects are minimized, informed consent is adequate and appropriately documented, and appropriate safeguards have been included to protect vulnerable subjects. 21 C.F.R. § 56.111.

regulations of the country in which the research was conducted. [21 C.F .R. §312.120(c)(1) (2001)].

70. In addition, all foreign clinical trials must conform to the standards of Good Clinical Practice.

1. **Regulations Applicable to Clinical Research Conducted in the U.S.**

71. The FDA has defined the required elements of informed consent to include:

> (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) a description of any reasonably foreseeable risks or discomforts to the subject; (3) a description of any benefits to the subject or to others which may reasonably be expected from the research; (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. . . ; (6) for research involving more than minimal risk, an explanation as to whether any compensation [sic] and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) an explanation of whom to

> contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research related injury to the subject; and (8) a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. 21 C.F.R § 50.25(a).

72. Further, FDA regulations require that informed consent be documented in a written consent form approved by an IRB, signed and dated by the subject or the subject's legally authorized representative at the time of the consent, unless such requirement has been specifically waived. 21 C.F.R §§ 50.27, 56.109 (2001).

73. FDA regulations also provide heightened protections for children in clinical investigations. Clinical investigations involving greater than minimal risk to children must present the prospect of direct benefit to individual subjects and such risk must be justified by the anticipated benefit to the subjects, the relation of the anticipated benefit must be as favorable as available alternative approaches, and adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians.

74. Under FDA regulations,

> no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has

> obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative.

21 C.F.R. § 50.20 (2001).

75. Also according to FDA regulations, when the study subject population includes non-English speaking people or the clinical investigator or the IRB anticipates that the consent interviews will be conducted in another language, the IRB should require a translated consent document to be prepared and assure that the translation is accurate. A copy of the consent document must be given to each subject, in the language understood by the study subject.

76. FDA regulation 21 C.F.R. § 56.107(e) (2001) prohibits any member of a clinical investigation team from participating in IRB review of any study except to provide information to the IRB because of potential conflict of interest.

77. When a proposed change in a research study is not minor (e.g., procedures involving increased risk or discomfort are to be added), then an IRB must review and approve the proposed change

at a convened meeting before the change can be implemented. The only exception is a change necessary to eliminate apparent immediate hazards to the research subjects. (21 C.F.R. § 56.108(a)(4)(2001)). In such a case, the IRB should be promptly informed of the change following its implementation and should review the change to determine that it is consistent with ensuring the subjects' continued welfare.

78. Although the FDA does provide an exception from the informed consent requirement in emergencies, that exception requires that both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing that: (1) the subject was confronted by a life threatening situation; (2) informed consent cannot be obtained because of an inability to communicate with or obtain legally effective consent from the subject; (3) time is not sufficient to obtain consent from the subject's legal representative; and (4) no alternative method of approved or generally recognized therapy is available that provides an equal or greater likelihood of saving the subject's life. 21 C.F.R. § 50.24.

79. Pfizer's conduct in Nigeria in the Kano Trovan Test was subject to FDA regulations because such regulations are conduct regulating and because the FDA regulations are expressly incorporated by the CIOMS Guidelines.

80. The Nuremberg Code, article 7 of the ICCPR, the Declaration of Helsinki, the CIOMS Guidelines and the FDA regulations set forth the minimum United States and international standards of conduct governing biomedical research on human

subjects, and constitute international customary law, norms of international law or the law of nations.

81. Furthermore, the proposition that international customary law prohibits medical experimentation on humans without their consent is indisputable. In addition to those international agreements discussed above, this principle is enshrined in numerous other international treaties and covenants.[5]

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[5] *See, e.g.*, the Multilateral Treaty for the Protection of War Victims: Prisoners of War, 6 U.S.T. 3316; 1949 U.S.T. LEXIS 483, at *13 (Feb. 2, 1956) (provides that "no prisoner of war may be subjected to physical mutilation or to medical or scientific experiments of any kind which are not justified by the medical, dental or hospital treatment of the prisoner concerned and carried out in his interest"); Multilateral Treaty for the Protection of War Victims: Civilian Persons, 6 U.S.T. LEXIS 3516, No. TIAS-3365, 1949 U.S.T. LEXIS 484, at *23 (Feb. 2, 1956) (prohibiting medical or scientific experiments not necessitated by the medical treatment of a protected person"); Principles of Medical Ethics relevant to the Role of Health Personnel, particularly Physicians in the Protection of Prisoners and Detainees against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment, Adopted by the United Nations General Assembly Resolution 37/194 of Dec. 18, 1982, at Principle 2 ("It is a gross contravention of medical ethics, as well as an offence under applicable international instruments, for health personnel, particularly physicians, to engage, actively or passively, in acts which constitute participation in,

2. **Relevant Standards of Good Clinical Practice**

82. Good clinical practice in clinical research requires that patients should have a complete history and physical examination at entry, both to confirm the diagnosis under study and to exclude other diagnoses.

83. The standard of care for bacterial meningitis requires that a central spinal fluid analysis ("CSF"), or lumbar puncture, and a Gram's stain blood test, be performed to diagnose the disease.

84. A log of all potential patients should be kept, but only those with CSF analysis/Gram's stain consistent with a bacterial meningitis diagnosis should be enrolled in the study.

85. Exclusion criteria should be used to exclude: (1) patients who do not have the disease under the study, (2) patients whose disease has progressed to a stage where drug intervention may be too late or inadequate, (3) patients who have a

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complicity in, incitement to or attempts to commit torture or other cruel, inhuman or degrading treatment or punishment"); Multilateral Treaty for the Protection of War Victims: Armed Forces in the Field, art. 12, 6 U.S.T. 3114, No. TIAS-3362, 1949 U.S.T. LEXIS 479, at *10 (Feb. 2, 1956) (members of the armed forces "shall not be . . . . subjected to torture or to biological experiments; they shall not willfully be left without medical assistance and care, nor shall conditions exposing them to contagion or infection be created.").

potentially unacceptable risk of adverse effects, and (4) patients with a serious underlying disease such that the risk of participation in the study may not result in a benefit for either the patient or the study outcome.

86. In non-U.S clinical studies involving bacterial meningitis, the standard of care provided should be similar to that provided to patients in the United States. The guidelines for good clinical practice for conducting meningitis experimentation do not support testing in facilities lacking basic hygiene, diagnostic equipment, and sufficient medical staff.

87. Industry guidelines governing meningitis experiments also call for a second CSF analysis a day or two after treatment begins to ensure that the patient is responding to treatment.

88. Industry guidelines for good clinical practice for conducting meningitis experiments do not support testing during an epidemic.

89. After treatment for bacterial meningitis, further follow-up visits for assessment of hearing, physical and neurological status should be conducted at five to six weeks and at five to seven months after completion of therapy.

90 A study outcome must be sound, clearly written and thoroughly developed. The protocol serves as the template for all procedures, tests or steps that are undertaken; all data collected; and all the information that is recorded during the course of a trial.

91. A good protocol does not automatically ensure a well-conducted clinical trial. The clinical trial will only be successful and its results plausible if the protocol is carefully followed, if protocol compliance is high, and if protocol violations are kept to a minimum. Information requested under the protocol should be obtained and documented under conditions and in time frames specified in the protocol.

92. Consent forms should be written in compliance with FDA guidelines and should completely and clearly explain risks versus benefits of enrollment in the study.

93. In pediatric trials, special attention should be given to obtaining consent.

94. A signed informed consent document is evidence that the document has been provided to a prospective subject and presumably explained and that the subject has agreed to participate in the research. IRB review of informed consent documents also ensures that the institution has complied with applicable guidelines.

## V. SUBSTANTIVE AL LEGATIONS

### A. Background

95. Trovafloxacin mesylate, which Pfizer sells under the brand name "Trovan," is a broad spectrum quinolone class antibiotic developed and synthesized by Pfizer. It is believed that Trovan attacks bacteria responsible for a wide range of illnesses.

96. At the time of its development in the mid-1990s, Trovan was expected to be an important

new product for Pfizer. Wall Street analysts predicted that Trovan could be one of the most financially successful drugs of its kind in years and that Pfizer, which had total annual sales of $16.2 billion in 1999, could reap an additional $1 billion per year if Trovan was approved by the FDA for all its potential uses.

97. Beginning in 1996, in order to obtain FDA approval for all of Trovan's potential uses, Pfizer conducted the largest testing program ever undertaken, enrolling thousands of people world-wide in clinical tests of Trovan.

98. Pfizer was aware that Trovan had the potential to cause significant side effects in children, as other quinolone class antibiotics have been shown to cause joint damage in animal studies. Prior animal studies showed that Trovan, when administered to immature rats and dogs, caused joint disease, abnormal cartilage growth, and osteochondiosis, which is characterized by degeneration of the cartilage and bone followed by defective bone formation in the growing portion of the skeleton, and can be crippling.

99. Pfizer also knew that Trovan was associated with liver toxicity prior to the conception and launch of the Kano Trovan Test. In animal studies, Trovan caused liver changes in all rats who received the drug, and no safe dosage was established for the species. In one canine experiment, liver damage occurred in one-quarter of subjects administered Trovan. Further, the signal and presence of adverse effects on the liver existed in clinical trials on the human population

100. As a result, Pfizer knew that it would need extensive, convincing tests that proved Trovan was safe and effective in order to secure approval for Trovan to be used on children.

101. To that end, in early 1996, Dr. Scott Hopkins, the Group Director for anti-infective clinical development at Pfizer Central Research in Groton, Connecticut, learned from an Internet site that an epidemic of bacterial meningitis was raging in Northern Nigeria. Bacterial meningitis is a serious infection of the brain and spinal cord for which effective remedies already exist. Northern Nigeria was also under siege in 1996 by concurrent cholera and measles epidemics for which effective remedies also exist.

102. Sensing an ideal opportunity to test Trovan on human subjects, Dr. Hopkins proposed to senior Pfizer executives that he lead a six person team to Kano, Nigeria to establish that Trovan in oral form could work as well in children as a fast-acting intravenous antibiotic already proven effective.

103. Kano is an impoverished city of two million people in northern Nigeria, a country which during 1996 was beset by civil strife and governed by a dictator, General Sani Abacha.

104. Pfizer authorized the proposal for the Kano Trovan Test, which if successful, would have paved the way for Pfizer to seek FDA approval for the marketing of Trovan to treat non- meningitis infections in children in the U.S. -- a potentially lucrative outlet for the drug for Pfizer.

105. Prior to the Pfizer Kano Trovan Test, only one child had ever been given Trovan, and that was for "compassionate reasons," that is, because all other antibiotics had failed.

106. At the time, no child had been given the oral formulation of Trovan.

**B. Pfizer Begins its Kano Trovan Test**

107. Within six weeks of discovering the existence of the meningitis epidemic in Northern Nigeria, Pfizer had assembled a protocol for its Kano Trovan Test. This timing was unusual in that such protocols usually take a year or more to develop. Pfizer informed the FDA of its intent to conduct the study under the export waiver option on March 15, 1996.

108. Before Trovan could be exported to Nigeria for a clinical trial, Pfizer needed to secure FDA authorization for export. For such purposes, Pfizer obtained the required letter of request from the Nigerian government which was received by the FDA on March 20, 1996.[6] Later that day, the FDA released Trovan for export to Nigeria.

109. Thereafter, in or about April, 1996, Pfizer researchers chartered a DC-9 and departed for Kano's Infectious Disease Hospital ("IDH") to begin

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[6] In addition to providing the requisite request for a clinical trial letter to the FDA, Nigeria's dictatorship facilitated Pfizer's efforts to conduct the Kano Trovan Test, among other things, arranging for Pfizer's accommodation in Kano, and acting to silence Nigerian physicians critical of the Company's Test.

testing of Trovan on children. Pfizer's Kano Trovan Test team consisted of three U.S. physicians, including Dr. Hopkins and his wife, who is also a physician; and four Nigerian doctors, including, Dr. Isa Dutse, a Nigerian infectious disease specialist.

110. Kano's IDH is very different from western concepts of an infectious disease hospital. It is a collection of several single story cinder block buildings, some of which lack electricity and running water. At the time of Pfizer's arrival, the conditions at IDH were squalid, as the hospital was overwhelmed by patients seeking care. All of the hospital's beds were filled, and patients seeking care overflowed onto the grounds of the hospital.

111. Prior to Pfizer's arrival in northern Nigeria, MSF had journeyed to Kano's IDH Hospital, to offer humanitarian treatment. Because of space constraints, MSF established their headquarters in a tent on IDH grounds. To combat bacterial meningitis, MSF dispensed chloramphenicol, a relatively inexpensive antibiotic. Notably, chloramphenicol is the drug recommended by the World Health Organization for treatment of bacterial meningitis in epidemic situations like that in Kano.

112. MSF had organized a treatment plan such that the sickest patients were admitted to hospital beds and the less ill confined to mats in tents erected throughout the hospital grounds.

113. When Pfizer's Kano Trovan Test team arrived at IDH, they were provided with control over two of IDH's wards to conduct the Kano Trovan Test. Pfizer was also provided with use of the hospital's nurses and doctors.

114. Pfizer's Kano Trovan Test team utilized a Nigerian nurse from the Kano area, Mahmoud Hassan. Hassan worked with the Pfizer doctors on-site who conducted the test.

115. Pfizer selected patients between one and thirteen years of age from among the children seeking help at the hospital to participate in the Kano Trovan Test. Pfizer chose patients who came to the hospital with neck stiffness, joint stiffness and/or high fever with headache.

116. Plaintiffs and the other patients who received treatment from Pfizer interacted with Mahmoud Hassan, who spoke both English and Hausa, the local language. Mahmoud Hassan was the only member of the Pfizer team who spoke Hausa, and thus the only member of the Pfizer team who was capable of communicating with the children who were chosen for the Kano Trovan Test and their families, most of whom spoke no English.

117. Neither Hassan nor any other Pfizer team member informed plaintiffs, the other patients who received treatment from Pfizer, or their guardians, that Pfizer was offering an experimental treatment.

118. Further, no Pfizer representative offered or read any informed consent document to plaintiffs.

119. Plaintiffs and their families were never informed that the treatment the children were to receive was experimental or that they had the option of receiving alternative treatment provided by MSF, which was available only a few steps from where Pfizer's treatment was being given.

120. The children treated by Pfizer were taken alone, without their parents, to the IDH ward run by Pfizer. The windows on that ward were covered and a screen erected so that the parents and the guardians of the children being treated could not see what the Pfizer team was doing to their children. After treatment was completed, a Pfizer team member brought the child back to his or her parents and provided them with a card, which set forth a number corresponding to the patient's identification number in the Trovan experiment. No data indicating what treatment the child had received was provided to the plaintiffs.[7]

121. Pfizer "treated" approximately 200 Nigerian children in its Kano Trovan Test. Five patients who were given Trovan died. Six patients in the control group, who were given inadequate doses of ceftriaxone, died.

122. After approximately two weeks of compiling data to be used in the United States, Pfizer's team left the IDH Hospital and Kano. Pfizer's employees never returned and did no follow-up evaluation of the participants in its experiment.

123. As described above, Pfizer's conduct in carrying out the Kano Trovan Test constituted cruel,

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[7] Many of these cards have been lost due to the passage of time, local custom (following a person's death in Nigeria, all of his or her belongings, including clothing and personal effects, are given away), or by giving the cards to other doctors at a later date when seeking treatment for the ill-effects of the Kano Trovan Test.

inhuman and degrading treatment of Plaintiffs and the other study enrollees, and violated the law of nations and treaties of the United States.

### C. Pfizer's Deviation From its Own Protocol and Violation of International Law

#### 1. The Company's Deviation from the Protocol

124. Pfizer's Kano Trovan Test protocol called for half of the patients to get Trovan. The other half were to receive an injection of ceftriaxone, an effective meningitis drug FDA-approved for children, which was manufactured by Hoffman-La Roche. According to its prescribing guidelines, ceftriaxone should be injected in a vein or muscle.

125. However, during the Kano Trovan Test, Pfizer did not administer the ceftriaxone as recommended. The Company reduced the amount of ceftriaxone it dispensed to one third of the recommended dosage. After learning of Pfizer's decision to sharply deviate from the recommended dosage, Hoffman-La Roche's medical director stated that "a high dose is essential" and that "*clinical failures . . .and perhaps deaths of children could have resulted from the law dosing.*"

126. Pfizer's protocol called for children enrolled in the experiment to have their blood tested on arrival and five days thereafter, and called for the children in the Kano Trovan Test receiving Trovan to be switched to ceftriaxone if such children did not respond well to the Trovan. However, during the actual experiment, Pfizer did not regularly analyze blood samples from patients. Thus, Pfizer could not

accurately determine which patients were not responding well to Trovan until such patients suffered visible, permanent injuries.

127. Pfizer's protocol called for Pfizer to obtain signatures of witnesses attesting to the oral consent of the patients that chose to participate in the trial. Further, Pfizer researchers had crafted a consent form to be used to secure the consent of the parents of the children enrolled in its experiment. The form was never used. Pfizer now contends that the children were too young to sign the forms and their parents could not speak or read English.

128. Pfizer's protocol called for patients arriving at the facility to be informed of their option to take part in the study, and to be given the option of choosing alternative treatment. Pfizer did not inform patients that it was conducting an experiment and their participation was optional or that alternative treatment was available on site from MSF.

129. Pfizer's protocol called for patients to be informed that the Kano Trovan Test involved comparing two different treatments for meningitis, one of which was experimental. However, Pfizer did not inform patients that they would be given one of two treatments, one of which was experimental.

### 2. Pfizer's Violation of International Law

130. In violation of Principle 1 of the Nuremberg Code, the Declaration of Helsinki, article 7 of the ICCPR, and FDA regulations, Pfizer failed to obtain informed consent, in either Hausa or English, from patients or their guardians before enrolling the

children in the Kano Trovan Test. In addition, Pfizer failed to explain to the children enrolled in the Kano Trovan Test and their parents and/or guardians the nature of the Kano Trovan Test, its purpose, and the risks, benefits, hazards, and inconvenience likely to be associated with the experiment, and failed to ensure that the subjects of the test understood they were free to refuse to participate in the study. Medical personnel, including a physician who participated in the Kano Trovan test, have acknowledged that the patient`s enrolled in the Kano Trovan study did not understand that they were being enrolled in a medical experiment. A Kano laboratory technician who took part in the Kano Trovan Test has specifically stated that, "[t]he patients did not know if it was research or not. They just knew they were sick."

131. Pfizer violated the Declaration of Helsinki, and FDA regulations, by failing to have an IRB review and approve its experimental protocol. Pfizer contends that the Company sought and received approval for the Kano Trovan Test from the Nigerian government and from an ethics committee at Kano Hospital where it intended to carry out the test. The letter Pfizer allegedly secured for this purpose from the Amino Kano Teaching Hospital was dated March 28, 1996.

132. However, contrary to Pfizer's version of events, according to the Aminu Kano Teaching Hospital's medical director, Dr. Sadiq Wali, the March 28, 1996 letter was back-dated and, in fact, at the time its approval was supposedly granted, the Hospital had no ethics committee. According to published reports, the so-called "approval" letter was

not created until years later. Further, Dr. Wali has stated that the stationery bearing his name and the letterhead of the ethics committee was not created until months after the "date" of the Pfizer letter.

133. In fact, Dr. Abdulhamid Isa Dutse, a Nigerian physician whom Pfizer says was its principal investigator for the Test, has admitted that his office created the backdated ethics approval document that Pfizer used to respond to a 1997 FDA audit. Dr. Dutse contends that the letter reflected the informal approval of three Nigerian physicians who had reviewed Pfizer's test plans and had no objections to them. However, Dr. Idris Mohammed, one of the three Nigerian physicians whom Dr. Dutse contends provided such approval, has publicly denied providing such approval, but rather states that he tried to stop the Kano Trovan Test.

134. Pfizer violated Principle 1 of the Nuremberg Code, the Declaration of Helsinki, article 7 of the ICCPR, and FDA regulations by failing to inform plaintiffs of the possible effects upon health from participation in the experiment, particularly the risks of joint damage and liver damage which Pfizer knew to be associated with drugs in Trovan's class and the risk associated with inadequate doses of ceftriaxone.

135. Pfizer violated Principle 4 of the Nuremberg Code, and the Declaration of Helsinki, by failing to provide testing to evaluate joint and liver damage in patients enrolled in the Kano Trovan Test, both before and after treatment. As described above, Pfizer was aware that Trovan had the potential to cause serious liver injury. Yet Pfizer failed to evaluate patients for liver damage prior to

or after enrollment in the Kano Trovan Test. Also, because quinolone antibiotics are known to have the potential to cause joint problems and arthritis, researchers conducting studies involving these drugs have used joint specialists to search for damage. Specifically, Pfizer has required MRI examinations of joints and examinations by orthopedic specialists in trials of quinolone antibiotics in the United States. However, Pfizer did no such evaluation of the Nigerian children enrolled in its experiment. Although Pfizer's report concludes that Trovan did no harm to enrolled children's joints, Pfizer's own report states that children who were given Trovan showed signs of joint pain three times the rate of children who took the control drug. Further, a European Union report concluded that this three times higher rate for arthralgia cannot be explained by mere chance or disbalanced study groups. While a Pfizer spokeswoman has since stated that a Nigerian ethics committee decided that there was no need to warn Nigerian parents that young lab animals given Trovan-class antibiotics had suffered joint damage, as discussed above, it is now evident that there was no such Nigerian ethics committee.

136. Pfizer violated Principles 4, 5, 6 and 10 of the Nuremberg Code, and the Declaration of Helsinki, which, inter alia, prohibit the continuation of an experiment that will likely result in injury, and the Hippocratic oath, which directs physicians to "first, do no harm." During the Kano Trovan Test Pfizer did not change the drug or dosage given to children whose condition worsened and failed to administer sufficient ceftriaxone in safe and efficacious amounts to patients to combat their disease. For example, one child, referred to as No.

0069, whose strength evaporated and whose one eye froze in place a day after being administered 56 milligrams of Trovan, died on the third day after treatment began. Pfizer's records indicate "Action taken: Dosage continued unchanged, Outcome: Death."

137. Pfizer violated, inter alia, Principles 4, 5, 6 and 10 of the Nuremberg Code, and the Declaration of Helsinki, by failing to provide alternative treatments to patients who did not respond to the drug administered, and by failing to provide all patients with the best proven diagnostic and therapeutic methods relevant to treating bacterial meningitis, including chloramphenicol, the drug recommended by the World Health Organization for treatment of epidemic bacterial meningitis.

138. Pfizer violated Principles 7 and 8 of the Nuremberg Code and the Declaration of Helsinki by: (1) failing to design and conform the Kano Trovan Test to a clearly formulated experimental protocol in compliance with generally accepted scientific principles; (2) failing to secure guidance on such protocol from a specially appointed independent committee; (3) carrying out the Kano Trovan Test in an inadequate facility lacking proper sanitation, electricity, and medical supplies; and (4) carrying out the experiment with improperly trained, inexperienced, and inadequate staff.

139. Pfizer violated article 7 of the ICCPR, the Nuremberg Code and the Declaration of Helsinki by, inter alia, subjecting the children to cruel or inhuman treatment by: (1) administering painful medical treatments without first obtaining consent;

(2) administering only a third of the recommended dosage of ceftriaxone to patients in the control group, enabling such patients' meningitis to continue unabated; (3) administering Trovan, a drug known to cause liver damage and joint problems, to unsuspecting children; and (4) failing to conduct adequate follow-up examinations to determine the injuries caused by the Kano Trovan Test.

140. Pfizer violated Principle 3 of the Nuremberg Code and the Declaration of Helsinki by failing to have sufficient experience or knowledge related to the natural history of the strain of bacterial meningitis present in Kano prior to undertaking the Kano Trovan Test. In fact, Pfizer prepared its study protocol in just six weeks after learning of the epidemic.

### 3. Pfizer's Own Experts Corroborate Pfizer's Violations of International Law and Federal Regulations

141. Pfizer's failure to comply with international law, FDA regulations and medical ethics has been publicly recognized by one of Pfizer's own pediatric infectious diseases specialist who was involved in the Kano Trovan Test.

142. In a complaint filed in Federal Court in the District of Connecticut, on May 18, 1998,[8] Dr. Juan Walterspiel, a pediatric infectious disease specialist who was employed by Pfizer during the relevant time and oversaw the pediatric trials of

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[8] *Walterspiel v. Pfizer, Inc.*, No. 3:98CV917 (JCH) (D. Conn. filed May 18, 1998) (complaint).

Trovan, has asserted that the Kano Trovan Test violated international law, and that he had so informed Pfizer. In his complaint, Dr. Walterspiel stated that he informed Pfizer senior management, on numerous occasions before, during, and after the Kano Trovan Test, that the experiment was violative of international law, federal regulations and ethical standards, and that Pfizer's methods could result in life-threatening illnesses and deaths to the children enrolled.

143. Specifically, Dr. Walterspiel complained that Pfizer failed to obtain proper informed consent, failed to provide adequate follow-up care, failed to conduct proper initial screening tests, failed to screen patients for kidney failure and hemolylitic anemia, utilized inexperienced staff unable to provide adequate patient care, and, in a conflict of interest, Pfizer physicians participated in the trial.

144. Dr. Juan Walterspiel detailed his objections to the Kano Trovan Test in a letter to Pfizer's Chairman and President of its Research Facility, in which he stated:

- the [Kano-Trovan] study conducted on children in Nigeria (154 149) was in violation of ethical rules for the conduct of medical experiments in humans.
- The oral formulation had never been given to children before.
- Some of the children were in critical condition and most of them malnourished, which made oral absorption even more

unpredictable. At least one died after a single oral dose; such a patient in critical condition should never have received an experimental antibiotic orally.

- The *N.meningitidis* serogroup A strain that caused the epidemic was not tested for its sensitivity before the first child was exposed to a **live or die experiment**.
- Quinolones are known to cause chrondrotoxicity [joint problems] in juvenile animals, especially in those with nutritional Mg deprivation (see our review in CID 1997; 25:1196-1204). Nevertheless, children exhibiting joint symptoms were not excluded from entry into the study, nor was trovafloxacin discontinued when joint symptoms developed under the treatment with trovafloxacin. The potential additive effect of immuncomplex disease and quinolone induced cartilage lesions have never been examined.
- Almost one hundred children were exposed to an experimental agent within a very short period of time, extending the risk for unknown short or long term adverse events to an unacceptably large number of

human beings, that predictably could not be followed.

- Inexperienced staff, *e.g.* coma score reversed, lack of experience in pediatric joint evaluation, blood drawing, placing iv lines, insufficient facilities and the vagaries for follow up, should have been obvious at the onset of the study, limiting any meaningful scientific data to be obtained.

  The 15% incidence of arthralgia in the trovafloxacin arm, versus 5% with ceftriaxone, now poses the dilemma that the drug indeed might have an arthropathic effect in children, or that these numbers are just the results of bad science and unreliable medical assessment.

- It is objectionable that Pfizer employees were allowed to participate in a medical study themselves. The potential for conflict of interest is obvious and a physician-patient relationship forced into existence under such circumstances is in opposition to the Hippocratic tradition.

- Apart from omissions in the consent form (e.g. the oral formulation has never been

> tested in children before, and when one's child is randomized to receive ceftriaxone, she/he will experience considerabl[y] more pain, the forms were NOT signed by the translators/witnesses). This raises the question whether the physicians looked at the form to confirm consent before administering an experimental drug, or worse, it makes one wonder what parents were told for expediency's sake.
>
> I expect no less from Pfizer Inc. and its employees than to adhere to the ethical and scientific rules of medical research as clearly laid down in the Declaration of Helsinki.

Letter from Juan Walterspiel M.D. to William C. Steere, Jr., Chairman & CEO Pfizer, Inc. and Dr. George M. Milne, Jr., President, Central Research, Pfizer, Inc. (Dec. 18, 1997) (Ex. A to the *Walterspiel* Complaint) (emphasis added).

145. As described by Dr. Walterspiel, Pfizer violated the Nuremberg Principles, article 7 of the ICCPR, and the Declaration of Helsinki, for the reasons set forth above.

146. Not only did Pfizer fail to take appropriate action in response to the ethical and legal violations in the Kano Trovan study raised by Dr. Walterspiel, Pfizer fired Dr. Walterspiel in retaliation for his whistleblowing related to the Kano Trovan Test.

147. Physicians who worked on site at the Kano Trovan Test have publicly agreed with Dr. Walterspiel's indictment of Pfizer's conduct. For example, Dr Amir Imam Yola, a Nigerian physician, characterized the Kano Trovan Test as "a bad thing " However, Dr. Yola explained that he did not object to the study because the test seemed to have the backing of the Nigerian government and as a result, he "could not protest. The system you have in America and the system we have here, there is a wide gap. Freedom of speech is still not here [in Nigeria]."

148. In addition, Dr. Abdulhamid Isa Dutse, Pfizer's principal investigator on the project, has voiced concern about Pfizer's behavior in Kano. In an interview, he explained that Pfizer's conduct in the Kano Trovan Test "opened our eyes. . . . You are dealing with human beings, whether they are American children or they are Nigerian children. They are entitled to the best."

### 4. MSF's Criticism of Pfizer's Kano Trovan Test

149. In addition to Pfizer's own employees, other medical professionals have publicly condemned Pfizer's conduct in Kano, including medical personnel associated with the Nobel Prize-winning MSF. For example, Karen De Jonge, a Belgian nurse and the Kano field coordinator for MSF, has denounced Pfizer's decision to conduct an experiment during an epidemic, stating "[I]n an epidemic, where you have a very high number of cases who will die, you don't go and experiment. You are talking about human lives." De Jonge also pointed out that Pfizer took over the best maintained hospital wards at

DDH, and stated that because of Pfizer's conduct, "[v]ery, very sick people were outside who could have had a bed inside." Further, according to De Jonge, Pfizer procured the most experienced doctors and nurses for its experiment, leaving the humanitarian relief organization with fewer resources.

150. De Jonge was not alone in her criticism of Pfizer, nor was she the Company's harshest critic. Dr. Evariste Lodi, the MSF physician who headed the charity's humanitarian mission in Kano, has harshly characterized Pfizer's decision to fail to change treatment for patients not responding to the initial drug offered, stating, "[i]t could be considered murder." Further, Dr. Lodi stated, "[i]f I had the power, I would take away their medical licenses."

151. Dr. Lodi's comments were echoed by another MSF official, Marc Gastellu-Etchegorry, who characterized Pfizer's failure to offer other alternate treatment to non-responsive patients as a "mistake." He continued, "When the patient is declining step-by-step, you try to give them a fighting chance. It can look like murder if you don't."

## VI. PLAINTIFFS SUFFERED INJURIES PROXIMATELY CAUSED BY PFIZER'S KANO TROVAN TEST

152. As described above, Pfizer gave an unproven oral suspension or tablet formula of Trovan to critically-ill Nigerian children, despite the availability of alternative drugs that have been shown to be safe and effective to treat bacterial meningitis. Moreover, children in the control group were given dangerously inadequate doses of ceftriaxone, which could prevent the drug from

working effectively and cause serious injury and death. Many of these children died or became blind, paralyzed, brain-damaged and/or deaf. Further, Pfizer did not alter the therapy provided to children who did not respond to Trovan, despite the availability of alternative treatments, such as those being dispensed by MSF.

153. As described more specifically below, the following children were each enrolled in the Kano Trovan Test and suffered injuries as a result.

154. Lubabatu Abdullahi was an infant in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Lubabatu Abdullahi was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Lubabatu Abdullahi was separated from her parents and was enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Lubabatu Abdullahi to accurately diagnose her with bacterial meningitis. Pfizer did not provide Lubabatu Abdullahi or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Lubabatu Abdullahi and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

155. Neither Lubabatu Abdullahi nor her parents, including her mother Rabi Abdullahi, were informed that Pfizer was offering experimental

treatment or consented to such treatment. Lubabatu Abdullahi died soon after her treatment.

156. Abdullahi (Manufi) Salisu was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Abdullahi was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Abdullahi (Manufi) Salisu was separated from his parents and was enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Abdullahi (Manufi) Salisu to accurately diagnose him with bacterial meningitis. Pfizer did not provide Abdullahi (Manufi) Salisu or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Abdullahi (Manufi) Salisu and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

157. Neither Abdullahi (Manufi) Salisu nor his parents, including his father Salisu Abullahi, were informed that Pfizer was offering experimental treatment or consented to such treatment. Abdullahi (Manufi) Salisu became paralyzed after receiving the experimental Pfizer treatment. A year later, Abdullahi (Manufi) Salisu died from complications of his paralysis. Abdullahi (Manufi) Salisu received no follow up treatment from Pfizer.

158. Firdausi Abdullahi was an infant in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a

high fever. While waiting for treatment, Firdausi Abdullahi was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Firdausi Abdullahi was separated from her parents and was enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief Pfizer did not conduct sufficient testing on Firdausi Abdullahi to accurately diagnose her with bacterial meningitis. Pfizer did not provide Firdausi Abdullahi or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Firdausi Abdullahi and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

159. Neither Firdausi Abdullahi nor her parents, including her father Abdullahi Alasan, were informed that Pfizer was offering experimental treatment or consented to such treatment. Firdausi Abdullahi died soon after her treatment.

160. Suleiman Ali was a 4 year old girl in or about April 1996 when she was taken by her parents to IDH for treatment of a fever. While waiting for treatment, Suleiman was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. She was separated from her parents and was enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Suleiman Ali to accurately diagnose her with bacterial meningitis. Pfizer did not provide Suleiman Ali or her parents with basic information, either through a written consent form

or orally, about the Kano Trovan Test, or seek their informed consent for her participation in the experiment. Suleiman Ali and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

161. Neither Suleiman Ali nor her parents, including her father All Hashimu, were informed that Pfizer was offering experimental treatment or consented to such treatment. Shortly after the Kano Trovan team took Suleiman Ali from her parents and gave her treatment outside of their view, Suleiman Ali died.

162. Abdullahi M. Inuwa was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Abdullahi M. Inuwa was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Abdullahi M. Inuwa was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief Pfizer did not conduct sufficient testing on Abdullahi M. Inuwa to accurately diagnose him with bacterial meningitis. Pfizer did not provide Abdullahi M. Inuwa or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Abdullahi M. Inuwa and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

163. Neither Abdullahi M. Inuwa nor his parents, including his father Muhammadu Inuwa, were informed that Pfizer was offering experimental treatment or consented to such treatment. Abdullahi M. Inuwa died soon after his treatment.

164. Kabiru Isyaku was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Kabiru Isyaku was chosen for the Kano Trovan Test by Pfizer from a line of people seeking care at IDH. Kabiru Isyaku was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Kabiru Isyaku to accurately diagnose him with bacterial meningitis. Pfizer did not provide Kabiru Isyaku or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Kabiru Isyaku and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

165. Neither Kabiru Isyaku nor his parents, including his father Magaji Alh Ladan, were informed that Pfizer was offering experimental treatment or consented to such treatment. Kabiru Isyaku died shortly after receiving treatment from Pfizer.

166. Buhari Suleiman was a 3 year old boy in or about April 1996 when he was taken by his parents for treatment of a fever. While waiting for treatment, Buhari was chosen for the Kano Trovan

Test by Pfizer from among the people seeking care at IDH. Buhari Suleiman was separated from his parents and was enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Buhari Suleiman to accurately diagnose him with bacterial meningitis. Pfizer did not provide Suleiman or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for his participation in the experiment. Buhari Suleiman and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

167. Neither Buhari Suleiman nor his parents, including his father Suleiman Umar, were informed that Pfizer was offering experimental treatment or consented to such treatment. Soon after his treatment by Pfizer, Suleiman lost consciousness. Buhari Suleiman died a day after arriving at IDH, after receiving a single treatment from Pfizer.

168. Zainab Abdu was 11 years old in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Zainab Abdu was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Zainab Abdu was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Zainab to accurately diagnose her with bacterial meningitis. Pfizer did not provide Zainab or her

parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent to participation in the experiment. Zainab and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

169. Neither Zainab nor her parents including her mother, Hajia Abdullahi, were informed that Pfizer was offering experimental treatment, nor did they consent to such treatment. Zainab became deaf and mute after her treatment. These conditions are permanent. Zainab received no follow-up treatment from the Pfizer team.

170. Firdausi Abdullahi was an infant in or about April 1996 when she was brought to IDH after fainting and suffering from a high fever. While waiting for treatment, Firdausi Abdullahi was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Firdausi Abdullahi was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Firdausi Abdullahi to accurately diagnose her with bacterial meningitis. Pfizer did not provide Firdausi Abdullahi or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the Kano Trovan Test. Plaintiff Firdausi Abdullahi and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

171. Neither Firdausi Abdullahi nor her parents, including her father Abdullahi Madawaki, were informed that Pfizer was offering experimental treatment nor did they consent to such treatment. Shortly after being subjected to the Kano Trovan Test, Firdausi became a quadriplegic, losing all ability to move her limbs. She also suffered brain damage and became deaf and mute. These injuries are permanent. Firdausi Abdullahi received no follow-up treatment from the Pfizer team. Instead, the Kano Trovan Test team gave her only a card with a number on it and referred her to another hospital for further treatment.

172. Sani Abdullahi was 6 years old in or about April 1996 when he was taken by his parents to IDH hospital to seek treatment for a fever a few days after his sister Firdausi was admitted to that hospital. While waiting for treatment, Sani Abdullahi was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Sani Abdullahi was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Sani Abdullahi to accurately diagnose him with bacterial meningitis. Pfizer did not provide Sani Abdullahi or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Sani Abdullahi and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

173. Neither Sani Abdullahi nor his parents, including his father Abdullahi Madawaki were informed that Pfizer was offering experimental treatment or consented to such treatment. Shortly after being subjected to the Kano Trovan Test, Sani Abdullahi lost the ability to use his right arm and leg. These injuries are permanent. Sani Abdullahi received no follow-up treatment from the Pfizer team.

174. Abdullahi Ado was 4 years old in or about April 1996 when he was taken by his parents to IDH for treatment of a fever. While waiting for treatment, Abdullahi Ado was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Abdullahi Ado was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Abdullahi Ado to accurately diagnose him with bacterial meningitis. Ado was treated for two weeks at IDH. Pfizer did not provide Ado or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Ado and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

175. Neither Abdullahi Ado nor his parents, including his mother Aisha Ado, were informed that Pfizer was offering experimental treatment or consented to such treatment. Shortly after being subjected to the Kano Trovan Test, while he was being treated at IDH, Abdullahi Ado lost his hearing,

his sight and his ability to walk. Although there has been some improvement in his condition, Abdullah Ado remains deaf. Abdullahi Ado received no follow-up treatment from the Pfizer team.

176. Abdulmajid Ali was 3 years old in or about April 1996 when he brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Abdulmajid was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Abdulmajid was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Abdulmajid was treated by both white and black medical personnel acting under the direction of Pfizer. Upon information and belief, Pfizer did not conduct sufficient testing on Abdulmajid to accurately diagnose him with bacterial meningitis. Pfizer did not provide Abdulmajid or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Abdulmajid and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

177. Neither Abdulmajid nor his parents, including his father Alh. Yusuf Ali, were informed that Pfizer was offering experimental treatment or consented to such treatment. Abdulmajid All received no follow-up treatment from the Pfizer team. While Abdulmajid apparently recovered subsequent to his participation in the Kano Trovan Test, he may nonetheless have sustained serious physical injuries therefrom as Trovan has been

shown to cause arthritis and liver damage in children. However, the existence of such conditions cannot be diagnosed without expensive medical testing which is unavailable to Abdulmajid Ali. Further, the information as to whether Trovan or ceftriaxone, the study's control, was administered to Abdulmajid during the Kano Trovan Test is solely in Pfizer's possession.

178. Nura Muhammed Ali was 7 years old in or about April 1996, when he was brought by his parents to IDH hospital for treatment of a fever. While waiting for treatment, Nura was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. He was separated from his parents and was enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Nura Muhammed Ali to accurately diagnose him with bacterial meningitis. Pfizer did not provide Nura Muhammed Ali or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent to participation in the experiment. Nura Muhammed Ali and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

179. Neither Nura Muhammed Ali nor his parents, including his father Muhammad Ali, were informed that Pfizer was offering experimental treatment, nor did they consent to such treatment. Nura Muhammed Ali received no follow-up treatment from the Pfizer team. While Nura Muhammed Ali apparently recovered subsequent to

his participation in the Kano Trovan Test, he may nonetheless have sustained serious physical injuries therefrom as Trovan has been shown to cause arthritis and liver damage in children. However, the existence of such conditions cannot be diagnosed without expensive medical testing which is unavailable to Nura. Further, the information as to whether Trovan or ceftriaxone, the study's control, was administered to Nura during the Kano Trovan Test is solely in Pfizer's possession.

180. Umar Badamasi was 4 years old in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Umar was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Umar was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Umar was treated by white medical personnel acting under the direction of Pfizer. Upon information and belief, Pfizer did not conduct sufficient testing on Umar to accurately diagnose him with bacterial meningitis. Pfizer did not provide Umar or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Umar and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

181. Neither Umar nor his parents, including his father Malam Badamasi Zubairu, were informed that Pfizer was offering experimental treatment or consented to such treatment. Umar

received no follow-up treatment from the Pfizer team. While Umar apparently recovered subsequent to his participation in the Kano Trovan Test, he may nonetheless have sustained serious physical injuries therefrom as Trovan has been shown to cause arthritis and liver damage in children. However, the existence of such conditions cannot be diagnosed without expensive medical testing which is unavailable to Umar Badamasi. Further, the information as to whether Trovan or ceftriaxone, the study's control, was administered to Umar during the Kano Trovan Test is solely in Pfizer's possession.

182. Muhammadu Fatahu Danladi was 8 years old in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Muhammadu was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Muhammadu was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Muhammadu was treated by white medical personnel acting under the direction of Pfizer. Upon information and belief, Pfizer did not conduct sufficient testing on Muhammadu to accurately diagnose him with bacterial meningitis. Pfizer did not provide Muhammadu or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Muhammadu and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

183. Neither Muhammadu nor his parents, including his father Alhaji Danladi Ibrahim, were informed that Pfizer was offering experimental treatment or consented to such treatment. Muhammadu received no follow-up treatment from the Pfizer team. While Muhammadu apparently recovered subsequent to his participation in the Kano Trovan Test, he may nonetheless have sustained serious physical injuries therefrom as Trovan has been shown to cause arthritis and liver damage in children. However, the existence of such conditions cannot be diagnosed without expensive medical testing which is unavailable to Muhammadu. Further, the information as to whether Trovan or ceftriaxone, the study's control, was administered to Muhammadu during the Kano Trovan Test is solely in Pfizer's possession.

184. Dalha Hamza was an infant in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Dalha was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Dalha Hamza was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Dalha Hamza to accurately diagnose her with bacterial meningitis. Pfizer did not provide Dalha Hamza or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Dalha Hamza and her family were not informed that safe and effective alternative

treatments were available at IDH, without charge, through MSF.

185. Neither Dalha Hamza nor her parents, including her father Mala Hamza Gwammaja, were informed that Pfizer was offering experimental treatment or consented to such treatment. Dalha Hamza became deaf and mute after her treatment. These conditions are permanent. Dalha Hamza received no follow-up treatment from the Pfizer team.

186. Tasiu Haruna was a 5 year old boy in or about April 1996 when he was taken by his parents to IDH hospital to obtain treatment for a fever and neck stiffness. While waiting for treatment, Tasiu was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Tasiu Haruna was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Tasiu Haruna to accurately diagnose him with bacterial meningitis. Pfizer did not provide Tasiu Haruna or his parents with basic information, in oral or written form, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Tasiu Haruna and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

187. Neither Tasiu Haruna nor his parents were informed that Pfizer was offering experimental treatment or consented to such treatment. Tasiu Haruna became deaf and mute after his treatment. These conditions are permanent. Tasiu Haruna received no follow-up care from the Pfizer team.

188. Muhyiddeen Hassan was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Muhyiddeen was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Muhyiddeen Hassan was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Muhyiddeen Hassan to accurately diagnose him with bacterial meningitis. Pfizer did not provide Muhyiddeen Hassan or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Muhyiddeen Hassan and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

189. Neither Muhyiddeen Hassan nor his parents, including his father Tijjani Hassan, were informed that Pfizer was offering experimental treatment or consented to such treatment. Muhyiddeen Hassan became deaf and mute after his treatment. These conditions are permanent. Muhyiddeen Hassan received no follow-up treatment from the Pfizer team.

190. Kawu Adamu Ibrahim was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Kawu was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Kawu Adamu

Ibrahim was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Kawu Adamu Ibrahim to accurately diagnose him with bacterial meningitis. Pfizer did not provide Kawu Adamu Ibrahim or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Kawu Adamu Ibrahim and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

191. Neither Kawu Adamu Ibrahim nor his parents, including his father Malam Abamus Ibrahim Adamu, were informed that Pfizer was offering experimental treatment or consented to such treatment. Kawu Adamu Ibrahim became deaf and mute after his treatment. These conditions are permanent. Kawu Adamu Ibrahim received no follow-up treatment from the Pfizer team.

192. Sunusi Alh. Ibrahim was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Sunusi was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Sunusi Alh. Ibrahim was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Sunusi Alh. Ibrahim to accurately diagnose him with bacterial meningitis. Pfizer did not provide Sunusi

Alh. Ibrahim or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Sunusi Alh. Ibrahim and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

193. Neither Sunusi Alh. Ibrahim nor his parents, including his father Alhaji Ibrahim Haruna, were informed that Pfizer was offering experimental treatment or consented to such treatment. Sunusi Alh. Ibrahim became blind and partially paralyzed after his treatment. These conditions are permanent. Sunusi Alh. Ibrahim received no follow-up treatment from the Pfizer team.

194. Maryam Idris was an infant in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Maryam was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Maryam Idris was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Maryam Idris was treated by medical personnel acting under the direction of Pfizer. Upon information and belief, Pfizer did not conduct sufficient testing on Maryam Idris to accurately diagnose her with bacterial meningitis. Pfizer did not provide Maryam Idris or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Maryam Idris and her family were not informed that

safe and effective alternative treatments were available at without charge, through MSF.

195. Neither Maryam Idris nor her parents, including her father Malam Idris, were informed that Pfizer was offering experimental treatment or consented to such treatment. Maryam Idris became deaf, mute and partially paralyzed after her treatment. These conditions are permanent. Maryam Idris received no follow-up treatment from the Pfizer team.

196. Yusif Idris was 2 years old in or about April 1996 when he was brought to IDH for treatment of a high fever. While waiting for treatment, Yusif was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Yusif Idris was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on plaintiff Idris to accurately diagnose him with bacterial meningitis. Idris was treated for three days at IDH. Pfizer did not provide Yusif Idris or his parents with basic information, in oral or written form, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Yusif Idris and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

197. Neither Yusif Idris nor his parents, including his father Umar Idris, were informed that Pfizer was offering experimental treatment or consented to such treatment. Within a week of receiving treatment from Pfizer, Yusif Idris became

deaf and mute. These conditions are permanent. Plaintiff Idris received no follow-up care from Pfizer.

198. Hafsat Isa was 3 years old in or about April 1996, when she was taken to IDH by her parents for treatment of a high fever. While waiting for treatment, Hafsat was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Hafsat Isa was separated from her parents and was enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Hafsat Isa to accurately diagnose her with bacterial meningitis. Pfizer did not provide Isa or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Hafsat Isa and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

199. Neither Isa nor her parents, including her father Isa Muhammad Isa, were informed that Pfizer was offering experimental treatment nor did they consent to such treatment. Following the treatment she received from Pfizer, Hafsat Isa began suffering from convulsions and lost the use of her hand. These injuries are permanent and Isa continues to suffer from seizures. Hafsat Isa received no follow-up treatment from the Pfizer team.

200. Taju Isa was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Taju was chosen for the Kano Trovan Test by Pfizer from among the people seeking

care at IDH. Taju Isa was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Taju Isa to accurately diagnose him with bacterial meningitis. Pfizer did not provide Taju Isa or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Taju Isa and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

201. Neither Taju Isa nor his parents, including his father Malam Isa Usman, were informed that Pfizer was offering experimental treatment or consented to such treatment. Taju Isa became deaf and mute after her treatment. These conditions are permanent. Taju Isa received no follow-up treatment from the Pfizer team.

202. Hadiza Isyaku was an infant in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Hadiza was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Isyaku was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Isyaku to accurately diagnose her with bacterial meningitis. Pfizer did not provide Isyaku or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their

informed consent for participation in the experiment. Isyaku and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

203. Neither Isyaku nor her parents, including her father Isyaku Shuaibu, were informed that Pfizer was offering experimental treatment or consented to such treatment. Pfizer provided Isyaku with two weeks worth of oral medication. Two weeks following her first treatment, Hadiza Isyaku lost the ability to move her left hand and leg, lost her hearing and sight, and became brain damaged. While there has been some improvement in her condition, she remains permanently brain damaged.

204. Zahra'u Jafaru was an infant in or about April 1996 when she was brought by her parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Zahra'u was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Zahra'u Jafaru was separated from her parents and enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Jafaru to accurately diagnose her with bacterial meningitis. Pfizer did not provide Zahra'u Jafaru or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Zahra'u Jafaru and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

205. Neither Zahra'u Jafaru nor her parents, including her father Jafaru Baba, were informed that Pfizer was offering experimental treatment or consented to such treatment. Zahra'u Jafaru became deaf and mute after her treatment. These conditions are permanent. Zahra'u Jafaru received no follow-up treatment from the Pfizer team.

206. Anas Mohammed was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Anas was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Anas Mohammed was separated from his parents and enrolled in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Anas Mohammed to accurately diagnose him with bacterial meningitis. Pfizer did not provide Anas Mohammed or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Anas Mohammed and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

207. Neither Anas Mohammed nor his parents, including his father Malam Mohammed, were informed that Pfizer was offering experimental treatment or consented to such treatment. Anas Mohammed became partially paralyzed after his treatment. This condition is permanent. Anas Mohammed received no follow-up treatment from the Pfizer team.

208. Nafisatu Muhammed was 3 years old in or about April 1996 when she was brought by her parents to IDH hospital for treatment of a fever. While waiting for treatment, Nafisatu was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Nafisatu Muhammed was separated from her parents and was enrolled by Pfizer in the Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Muhammed to accurately diagnose her with bacterial meningitis Pfizer did not provide Muhammed or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent to participation in the experiment. Muhammed and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

209. Neither Nafisatu Muhammed nor her parents, including her father Yahawasu Muhammed, were informed that Pfizer was offering experimental treatment, nor did they consent to such treatment. Nafisatu Muhammed became deaf and mute after her treatment. These conditions are permanent. Nafisatu Muhammed received no follow-up treatment from the Pfizer team.

210. Asma'u Mustapha was 6 years old in or about April 1996, when she was brought by her parents to IDH hospital for treatment of a fever. While waiting for treatment, Asma'u was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH. Asma'u was separated from her parents and was enrolled by Pfizer in the

Kano Trovan Test without her family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Asma'u to accurately diagnose her with bacterial meningitis. Pfizer did not provide Asma'u or her parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent to participation in the experiment. Asma'u and her family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

211. Neither Asma'u nor her parents, including her father Alhaji Mustapha, were informed that Pfizer was offering experimental treatment, nor did they consent to such treatment. Asma'u received no follow-up treatment from the Pfizer team. While Asma'u apparently recovered subsequent to her participation in the Kano Trovan Test, she may nonetheless have sustained serious physical injuries therefrom as Trovan has been shown to cause arthritis and liver damage in children. However, the existence of such conditions cannot be diagnosed without expensive medical testing which is unavailable to Asma'u. Further, the information as to whether Trovan or ceftriaxone, the study's control, was administered to Asma'u during the Kano Trovan Test is solely in Pfizer's possession.

212. Muhsinu Tijjani was an infant in or about April 1996 when he was brought by his parents to the IDH hospital to seek treatment for a high fever. While waiting for treatment, Muhsinu Tijjani was chosen for the Kano Trovan Test by Pfizer from among the people seeking care at IDH.

Muhsinu Tijjani was separated from his parents and enrolled by Pfizer in the Kano Trovan Test without his family's consent or knowledge. Upon information and belief, Pfizer did not conduct sufficient testing on Muhsinu Tijjani to accurately diagnose him with bacterial meningitis. Pfizer did not provide Muhsinu Tijjani or his parents with basic information, either through a written consent form or orally, about the Kano Trovan Test, or seek their informed consent for participation in the experiment. Muhsinu Tijjani and his family were not informed that safe and effective alternative treatments were available at IDH, without charge, through MSF.

213. Neither Muhsinu Tijjani nor his parents, including his father Tijjani Hassan, were informed that Pfizer was offering experimental treatment or consented to such treatment. Muhsinu Tijjani became partially paralyzed after his treatment. This condition is permanent. Muhsinu Tijjani received no follow-up treatment from the Pfizer team.

214. Each of the plaintiffs who were subjects of the Kano Trovan Test and received Trovan may be suffering from undiagnosed liver damage and/or joint damage, which has been associated with Trovan. Pfizer did not perform an initial liver screen before administering Trovan, nor did it do liver monitoring tests to ensure that patients' livers were not damaged. The tests to determine the extent of each patients' liver injury are not widely or generally available in Nigeria. Furthermore, Pfizer did not conduct MRI or orthopedic examinations to test for joint damage in the patients administered Trovan. These tests also are not widely or generally available

in Nigeria. Rather, Pfizer ignored or mischaracterized as non-adverse events the evidence of joint pain and damage that was clearly present in the Kano Trovan Test data.

215. In addition, Plaintiffs who were subjects of the Kano Trovan Test and received improperly administered and/or inadequate dosages of ceftriaxone suffered consequences of an illness that otherwise would not have occurred.

## VII. TIMELINE OF REGULATORY ACTION CONCERNING TROVAN

216. On December 30, 1996, Pfizer filed an application with the FDA seeking approval to market Trovan in the United States for a variety of uses, including the treatment of infectious disease in children.

217. In or about June of 1997, FDA inspectors at Pfizer's Groton, Connecticut facility discovered nearly four dozen inconsistencies in Pfizer's data from the Kano, Nigeria experiment. Pfizer thereafter withdrew its application to use the drug against "epidemic meningitis," after regulators indicated they would deny it based on a range of concerns -- including the failure to conduct adequate follow-up exams.

218. Trovan was launched in February 1998 after receiving FDA authorization for a number of adult illnesses on December 17, 1997.

219. Soon after Trovan was approved, Pfizer and the FDA began to receive reports of Trovan patients suffering from liver damage.

220. In June 1999, the European Union's Committee for Proprietary Medicinal Products suspended all sales of Trovan for one year, a ban which was later extended.

221. Despite these reports, Pfizer continued to seek to market Trovan to children and in 1998 and 1999 was conducting tests of Trovan against bacterial meningitis in U.S. children, using in part the knowledge concerning the drug's toxicity in pediatric patients gained from the Kano Trovan Test.

222. The European Union has refused to allow Trovan to be marketed to children, in part based on the findings of the Kano Trovan Test.

223. In January 1999, the FDA recommended that Trovan be prescribed only to patients in nursing homes or hospital settings suffering from life threatening conditions.

224. On June 9, 1999, the FDA issued a public health advisory on liver toxicity associated with Trovan and Trovan-IV (the intravenous formulation of the drug) following post-marketing reports of acute liver failure strongly associated with the drug. The FDA informed physicians that Trovan should be reserved for use only in patients who meet three specific criteria, and that Pfizer had agreed to limit distribution of Trovan to hospitals and long term care nursing facilities.

225. The FDA advisory noted that the agency "had received reports of over 100 cases of clinically symptomatic liver toxicity in patients receiving Trovan. Some of the patients developed serious liver injury leading to liver transplant and/or death." The advisory also stated that "Trovan-

associated liver failure appears to be unpredictable and has been associated with as little as two days exposure."

226. The FDA action effectively pulled Trovan from general pharmacy shelves and restricted doctors to using Trovan in only emergency situations where the need to combat a serious, life-threatening infection outweighs any liver risk.

## VIII. FRAUDULENT CONCEALMENT/ TOLLING OF THE STATUTE OF LIMITATIONS

227. Defendant concealed from plaintiffs the relevant facts concerning the 1996 Kano Trovan Test. As described above, plaintiffs were unaware that their children and charges were subjects of an experimental Trovan trial and signed no consent forms related to that trial. Plaintiffs did not know, and could not have discovered, that they had participated in a biomedical research experiment until December 2000, when Nigerian newspapers reported the facts of the experiment first exposed by a December 17, 2000 article in The Washington Post written by Joe Stephens.

## IX. CLAIMS

### First Claim for Relief Under International Law Failure to Obtain Informed Consent

228. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

229. International Law as evidenced by, *inter alia*, the Nuremberg Code, the Declaration of

Helsinki, article 7 of the ICCPR, and the CIOMS Guidelines requires that medical researchers receive informed consent.

230. Defendant Pfizer did not secure plaintiffs' informed consent or in fact any consent prior to enrolling the plaintiff children in its test of Trovan.

231. As a result of defendant's actions, the children enrolled in the Kano Trovan Test and their parents suffered damages, including the right to withhold consent, the children's deafness, blindness, paralysis, mental and physical suffering and death, and the parents' mental suffering, cost of care and loss of services.

**Second Claim for Relief Under International Law Breach of Duty to Provide the Best Proven Diagnostic and Therapeutic Methods**

232. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

233. International Law as evidenced by, *inter alia*, the Nuremberg Code, the Declaration of Helsinki, and the CIOMS Guidelines requires that medical researchers provide the best proven diagnostic and therapeutic methods.

234. Defendant breached this duty by failing to properly diagnose patients as suffering from bacterial meningitis through the use of CFS

analyses, which is the internationally accepted method for diagnosing meningitis.

235. Defendant also breached this duty by abandoning efforts to test patients' blood as planned.

236. Defendant also breached this duty by giving Trovan to critically-ill Nigerian children, despite the availability of alternative, safer drugs.

237. Defendant also breached this duty by failing to alter the therapy provided to children who did not respond to treatment provided in the experiment and by failing to use alternative treatments for such children.

238. Defendant also breached this duty by purposefully low dosing (administering one-third of the recommended dosage) ceftriaxone to patients in the control group.

239. Defendant also breached this duty by failing to provide adequate follow-up care to patients enrolled in its experiment and by improperly injecting the control drug.

240. Defendant's above-referenced actions caused the children enrolled in the Kano Trovan Test and their parents to suffer damages, including the children's deafness, blindness, paralysis, physical and mental suffering, and death, and the parents' mental suffering, cost of care and loss of services.

**Third Claim for Relief Under International Law Breach of Duty to Treat with Dignity**

241. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

242. International Law as evidenced by, *inter alia*, the Nuremberg Code and Helsinki Declaration recognizes the right of every human subject to be treated with dignity in the conduct of a clinical trial.

243. Defendant's conduct during the Kano Trovan Test as set forth herein, breached plaintiffs' right to be treated with dignity as set forth in the Nuremberg Code and Declaration of Helsinki.

244. Defendant's actions caused the children enrolled in the Kano Trovan Test and their parents to suffer damages, including the children's deafness, blindness, paralysis, physical and mental suffering, and death, and the parents' mental suffering, cost of care and loss of services.

**Fourth Claim for Relief Under International Law Breach of Right to be Free from Cruel, Inhuman and Degrading Treatment**

245. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth herein.

246. International Law as evidenced by, *inter alia*, art. 7 of the ICCPR considers medical testing without informed consent as torture or cruel or inhuman punishment which is forbidden under International Law as evidenced by art. 5 of the Universal Declaration of Human Rights.

247. As described herein, Defendant conducted the Kano Trovan Test without seeking plaintiffs' informed consent, or in fact any consent from the children enrolled and/or their parents or guardians. Plaintiffs were not informed the

"treatment" provided to the children enrolled in the Kano Trovan Test was experimental in nature. Nevertheless, Pfizer enrolled the children in the Kano Trovan Test.

248. Defendant's conduct constituted torture or cruel or inhuman punishment in violation of the law of nations.

249. Defendant's conduct was intentional and/or reckless, and was so outrageous in character and extreme in degree as to go beyond all possible bounds of decency, and to be regarded as atrocious and utterly intolerable in a civilized community.

250. Defendant's conduct caused the children enrolled in the Kano Trovan Test and their parents to suffer damages, including the children's deafness, blindness, paralysis, physical and mental suffering and death, and the parents' mental suffering, cost of care and loss of services.

## X. INJUNCTIVE, EQUITABLE AND MONETARY RELIEF

251. Defendant has a continuing duty to warn plaintiffs and other subjects of the Kano Trovan Test of all potential risks and dangers of which it becomes or should become aware.

252. Defendant should be required to provide the children it experimented upon with ongoing testing to evaluate their liver function and/or damage and their joint function and/or damage.

253. Defendant should be enjoined from conducting further testing, pre-market or otherwise,

on any person, without first obtaining informed consent consistent with FDA regulations.

254. Defendants should be required to pay plaintiffs' compensatory damages.

## XI. ENTITLEMENT TO PUNITIVE DAMAGES

255. Plaintiffs are entitled to punitive damages because defendant's conduct was wanton and outrageous and because defendant acted with a motive to deceive plaintiffs and their young, sick, innocent children regarding the nature, safety and efficacy of the treatment being provided.

256. Plaintiffs are also entitled to punitive damages because of defendant's reckless indifference to the rights of the plaintiffs to make an informed consent prior to their children and charges being enrolled in a medical experiment.

257. Plaintiffs are entitled to punitive damages in that the test violated international law, federal law and medical ethical standards, but the Company took no corrective action.

258. Plaintiffs are further entitled to punitive damages because Pfizer chose as its victims sick and impoverished Nigerian children who were particularly vulnerable and thus deserving of special care and protection.

259. Pfizer, as the world's largest pharmaceutical company, with revenues of $16.2 billion in 1999, will not be deterred in the future from the type of conduct complained of herein unless very substantial punitive damages are imposed.

**WHEREFORE, PLAINTIFFS PRAY FOR RELIEF AS FOLLOWS:**

a. Award plaintiffs compensation arising from their nonconsensual involvement in the Kano Trovan Test;

b. An Order requiring defendant to pay punitive damages;

c. An Order requiring defendant to provide ongoing medical care to evaluate the liver and joint function of the children enrolled in the experiment and requiring defendants to treat any abnormalities so detected;

d. An Order enjoining defendant from conducting illegal human experimentation anywhere in the world;

e. Attorneys' fees, expenses, and costs of this action; and

f. Such further relief as this Court deems necessary, just, and proper.

**DEMAND FOR JURY TRIAL**

Plaintiffs demand a trial by jury in this action.

Dated: August 28, 2001

**MILBERG WEISS BERSHAD HYNES & LERACH LLP**

By s/ Melvyn Weiss
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**Attorneys for Plaintiffs**

## APPENDIX F

UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

CIVIL ACTION NO. 302CV02104 GLG

**COMPLAINT**
**AND JURY TRIAL DEMAND**

Ajudu Ismaila Adamu, Individually and as Parent and Natural Guardian of Yahaya Ismaica, A Minor

Malam Mohammed, Individually and as Parent and Natural Guardian of Bashir Mohammed, A Minor

Malam Yusub Ya'u Amale, Individually and as Parent and Natural Guardian of Suyudi Yusals Ya'u, A Minor

Zangon Kwajalawa, Individually and as Parent and Guardian of Nuruddim Dauda, A Minor

Malasm Haruna Adamu Individually and as Parent and Natural Guradian of Mohammed Tasi'u Haruna, A Minor

Malam Dahuru Ya'y Individually and as Parent and Natural Guardian of Rabi Dahuru, A Minor

Malam Dahura Ya'y Individually and as Parent and Natural Guardian of Zainab Musa Dahuru, A Minor

Malam Musas Zangon Marikita Individually and as Parent and Natural Guardian of Ismaila Musa, A Minor

Arhaji Muihammad Soja Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Hamza Achaji Muhammad, A Minor, Deceased

Achaji Ibrahim Dankwalba Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Abdullahi Ibrahim, A Minor, Deceased

Malam Lawan Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Jamilu Lawan, A Minor, Deceased

Alhaji Muhammed Tsohon Soja Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Ummi Alhasi Muhammed, A Minor, Deceased

Ismaila Zubairui Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Mustapha Zubairu, A Minor, Deceased

Malam Lawan Individually and as Parent and Natural Guardian of Habiba Lawan, A Minor

Abubakar Musa, Parent and Natural Guardian of Sa'adatu Musa, A Minor

Mohamed Abdu Individually and as Parent and Natural Guardian of Haruna Abdu, A Minor

Mallam Hassan Individually and as Parent and Natural Guardian Hajaran Hassan, A Minor

Mallam Mohamadu Jabbo Individually and as Parent and Natural Guardian of Auwalu Mohamadu Jabbo, A Minor

Mallam Yakubu Umar Individually and as Parent and Natural Guardian of Abubakar Yakubu, A Minor

Mallam Samaila Individually and as Parent and Natural Guardian of Adamu Samaila, A Minor

Musa Yahaya Individually and as Parent and Natural Guardian of Ukhasa Musa, A Minor

Audu Ismaila Adamu Individually and as Parent and Natural Guardian of Yashaya Samaila, A Minor

Malam Musa Dahiru Individually and as Parent and Natural Guardian of Zainabu Musa, A Minor

Malam Musa Zango Individually and as Parent and Natural Guardian of Samaila Musa, A Minor

Mallam Alhassan Maihula Individually and as Parent and Natural Guardian of Najib Maihula, A Minor

Mallam Yusus Gama Individually and as Parent and Natural Guardian of Dankuma Gama, A Minor

Mallam Abdullah Adamu Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Abdullah Adamu, A Minor, Deceased

Dauda Nuhu Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Hamisu Nuhu, A Minor, Deceased

Mallam Abdullahi Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Najaratu Abdullahi, A Minor, Deceased

Malam Umaru Mohammed Individually and as Parent and NaturalGuardian and Personal Representative of the Estate of Sule Mohammed, A Minor, Deceased

Mallam Nasiru Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Yusif Nasiru, A Minor, Deceased

Malam Hassan Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Nura Mohammed, A Minor, Deceased

Malam Hassan Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Adamu Mohammed, A Minor, Deceased

Maslam Hassan Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Sadiya Hassan, A Minor, Deceased

Mallam Lawan Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Aisha Lawan, A Minor, Deceased

Yusuf Musa Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Nafisatu Musa, A Minor, Deceased

Mallam Muritala Individually and as Parent and. Natural Guardian and Personal Representative of the Estate of Umaru Muritala, A Minor, Deceased

Mallam Tanko Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Madina Tankol, A Minor, Deceased

Mallam Sheu Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Aisha Sheu, A Minor, Deceased

Malam Kabiru Mohamed Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Kabiru Mohamed, A Minor, Deceased

Mallam Abdullahi Individually and as Parent and Natural Guardiah and Personal Representative of

the Estate of Rukiya Abdullahi, A Minor, Deceased

Mallam Sule Abubakar Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Fatima Abubakar, A Minor, Deceased

Mallam Idris Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Baba Idris, A Minor, Deceased

Mallam Mohamed Bashir Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Sani Bashir, A Minor, Deceased

Alhaji Ubah Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Maryam Ubah, A Minor, Deceased

Mallam Idris Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Aminu Idris, A Minor, Deceased

Mallam Hassan Ibrahim Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Hassan Ibrahim,, A Minor, Deceased

Alhaji Shuaibu Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Masjbatu Shuaibu, A Minor, Deceased

Mallam Abdullahi Sale Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Shamisiya Sale, A Minor, Deceased

Mallam Ibrahim Amyarawa Individually and as Parent and Natural Guardian and Personal Representative Of the Estate of Yahaya Ibrahim, A Minor, Deceased

Mallarn Abdu Abubakar Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Nasitu Abubakar, A Minor, Deceased

Mallam Yusuf Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Hodiza Yusuf, A Minor, Deceased

Mallam Dauda Yusuf Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Abubakar Sheu, A Minor, Deceased

Maliam Mohammed Sheu Individually and as Parent and NaturalGuardian and Personal Representative of the Estate of Mustapha Yakubu, A Minor, Deceased

Mallam Yakubu Ibrahim Individually and as Parent and Natural Guardian and Personal Representative of the Estate of Ashiru KIbrahim, A Minor, Deceased

Plaintiffs

V.

PFIZER, INC.,

Defendant

Plaintiffs, by their attorneys, make the following allegations based upon reasonable information and belief and pursuant to the investigation and information provided by and with the assistance of two Nigerian counsel Lukman Kunle Ishola, a Nigerian legal practitioner, partner in the law firm of Olajuwon, Omotimirin and

Associates and Etigwe Uwa of Stream, Sowers & Company, both of Lagos, Nigeria.

## I. JURISDICTION

1. This Court has jurisdiction pursuant to 28 U.S.C. § 1332. The plaintiffs are all citizens or subjects of a foreign state (Nigeria) whereas the defendant is a Delaware corporation with corporate headquarters in New York City, New York and its central research and development Headquarters for drug development in Groton and New London, Connecticut, and the amount in controversy exceeds $75,000.00.

2. This Court has jurisdiction pursuant to 28 U.S.C. 1331, which confers district courts with original jurisdiction over all civil actions arising out of the laws, including customary international law, and treaties of the United States.

3. This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1350, The Alien Tort Claims Act, which provides that "[t]he district courts shall have original jurisdiction of any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States."

4. The Alien Tort Claims Act allows aliens to bring actions against non-state actors for tort claims arising from violations of customary international law. See Kadic v. Karadzic, 70 F. 3d 232, 239 (2d Cir. 1995).

5. The plaintiffs are bringing this action within the District of Connecticut in the United States District Court also based on venue, §1391. This is the judicial district in which a substantial part of the events or omissions giving rise to the claim occurred and/or in which the defendant is subject to personal jurisdiction pursuant to §1391(a)(2) and/or §1391(b)(2).

## II. VENUE

6. The District Court of Connecticut is the proper venue for this action for several reasons:

(a) Pfizer's Trovan drug test was devised, created, largely implemented, executed and reviewed at its Research and Development Headquarters in Groton, Connecticut, and the research team that went to Nigeria largely, if not exclusively, came from said headquarters;

(b) The review of data and the key relevant witnesses for Pfizer, Inc. were or are located in said venue;

(c) This case is also brought under the Connecticut Unfair Trade Practices Act, which is unique to Connecticut;

(d) Connecticut Products Liability Act, which is unique to Connecticut;

(e) The Trovan treatment protocol was developed, strategized, produced, promulgated, performed and designed within the District of Connecticut;

(f) Previously filed in this Court, Walterspiel v. Pfizer, Inc., 98 CV 917 (JCH) filed May 18, 1998 and more specifically referred to within this complaint, which apparently was a whistle-blowing case brought by Dr. Juan Walterspiel against his employer Pfizer, Inc. for allegedly terminating him because he was one of the leading doctors involved in the Trovan drug testing program who complained, to Pfizer about what he believed to be its improprieties concerning the Trovan drug test which were discovered at the Groton, Connecticut facility of the defendant Pfizer, Inc.; See also paragraphs 23, 38 and 39 of this Complaint;

(g) On or about June, 1997 FDA inspectors at Pfizer's Groton, Connecticut facility discovered approximately 45 inconsistencies in the drug testing data from Kano, Nigeria;

(h) United Nations Universal Declaration of Human Rights in Article 8 seeks to provide effective remedy by the competent national tribunal for acts violating one's fundamental rights. (Writer's emphasis added.) It also recognizes that the remedy must be adjudicatory and that it guarantees the victim of human rights abuses his or her day in court. As stated later within this complaint, the plaintiffs hereby allege that they cannot find in the forum of the Country of Nigeria a truly adjudicatory forum that would guarantee

them the human rights abuses that they allegedly suffered nor that they will have their day in court or not without interminable delay. In the instant matter the Nigerian government acted in concert with Pfizer by providing a letter requesting the FDA to authorize the export of Trovan to Nigeria and arranging for Pfizer's accommodations at a Nigerian hospital in Kano, the IDH, assigning Nigerian physicians to assist in the project and also back-dating an approval letter that international protocol required to be ascertained prior to the test and said Nigerian government acted to silence the Nigerian physicians critical of the company's test. Thus, the Nigerian government and Pfizer were joint participants in the Trovan drug test treatment case involving the instant plaintiffs was filed in the Federal High Court in Kano in Nigeria. The Presiding Judge of the Federal High Court in Kano, Nigeria, of which there are only two sitting judges, was removed for corruption which caused a six- month period of inactivity in the lawsuit filed by the instant plaintiffs in Nigeria from November, 2001 through April, 2002. Then the second judge in the Federal High Court in Kano State temporarily took over the jurisdiction, but thereafter that judge handled the case only for a period of April, 2002 though July, 2002 and then during a hearing on a discovery motion delivered an initial ruling

in the case and in open court declined jurisdiction claiming that he had to do so for personal reasons which have still not been described nor disclosed. The Nigerian Judiciary had not posted any other judge to the Federal High Court since October, 2001 to the present date and the case was suffering an indefinite adjournment which is causing undue prejudice, particularly to those families of the deceased plaintiffs and particularly to those plaintiffs who are still alive and suffering from continuing and permanent physical deformities caused by the defendant's drug testing. Thus the plaintiffs through their Nigerian counsel discontinued their suit in the Nigerian court for want of diligent prosecution by the Nigerian courts and filed a Notice of Discontinuance on October 17, 2002. Thus the case brought by these very plaintiffs in the instant matter of our District Court of Connecticut found that justice had been delayed and now denied in Nigeria. The Nigerian court has therefore by its action and non-action declined to presently accept jurisdiction of this case. Even if it did, based on the allegations contained in this Complaint and representations made within this Venue section, the District Court of Connecticut in the United States is still the proper venue.

(i) Pfizer developed, produced and performed preliminary testing of Trovan and also designed the Kano treatment protocol all in the United. States and it is alleged that

Pfizer conducted those activities and allegedly circumvented FDA regulations with the ultimate goal of selling and distributing Trovan domestically in the United States, and much of the tortious activity referred to in this Complaint occurred in the District of Connecticut.

(j) Recently Judge Pauley in the United States District Court for the Southern District of New York, Case Number 01 CV 8118, relating to other plaintiffs from Nigeria that brought an action in that district denied the defendant's 12B6 Motion to Dismiss the case and agreed that the plaintiffs in that case had alleged that the defendant Pfizer violated customary international law and there was jurisdiction pursuant to the Alien Tort Claims Act that the complaint adequately pled a violation of international law. However, he ruled against the plaintiffs with regard to form non conveniens:

(1) although the plaintiffs in that action did not claim a product liability action;

(2) nor an unfair trade practice action unique to New York.

(3) He ruled before the Nigerian case relating to this incident in Nigeria was withdrawn for the reasons stated in Paragraph 6(h) above.

At the time of the decision in New York the plaintiffs in the instant case had filed an action in Nigeria but that case has been voluntarily dismissed because the first judge hearing the matter was released because of corruption unrelated to the case and the second judge who was assigned the case refused and still refuses to accept the case and the jurisdiction thereof for personal reasons which he will not describe. Thus the case brought by these very plaintiffs in the instant matter before the District Court of Connecticut represents justice delayed and now denied in Nigeria. Moreover, there are substantially more ties to the District of Connecticut for the reasons stated within this Complaint than New York, which limited tie seems to be that Pfizer, Inc., a Delaware corporation, has its corporate building headquarters in New York City, whereas the main headquarters for anti-invective clinical development of Pfizer's global research and development world headquarters is in Groton and New London, Connecticut, which is the location that developed and produced and performed the preliminary testing of Trovan and designed the Kano treatment protocol;

(k) This case is also brought under Connecticut General Statutes §52-595 which is a concealment statute unique to Connecticut.

(l) The defendant, Pfizer, Inc., is doing business within this Judicial District of Connecticut and therefore the subject of personal jurisdiction pursuant to 28 U.S.C. §1391(a)(2) and/or 28 U.S.C. §1391(b)(2);

(m) [sic]

## III. GENERAL ALLEGATIONS

7. The minor plaintiffs on behalf of this action being brought ppa by the respective parents and/or guardians alleging that some time in the early Spring of 1996 there was an outbreak of cholera, meningitis and gastroenteritis in the Kano area of northern Nigeria. At all material times to this suit the plaintiffs fell ill and were sent to the Infectious Disease Hospital in Kano, Nigeria.

8. The minor plaintiffs were subjected to an experimental drug test conducted by the defendant Pfizer, Inc. in Kano, Nigeria and said defendant never obtained a valid informed consent from the minor plaintiffs or their parents. The preparation, planning and execution of this test was conducted in violation of the Connecticut Fair Trade Practices Act (C.G.S. §42-110b, et seq.,), The Connecticut Products Liability Act (C.G.S. § 52-572m, et seq), violation of international laws and treaties, including the Nuremberg Code of 1947, The Declaration of Helsinki, The International Covenant on Civil and Political Rights, International Ethical Guidelines for Research Involving Human Subjects and its Council for International Organization of Medical Sciences Guidelines and rules governed by FDA regulations.

9. The injuries suffered by the minor plaintiffs as a result of Pfizer's secret and improper testing include among other things, brain damage, loss of hearing, loss of sight, loss of motor skills, psychological and emotional trauma, branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, and in some cases amputation of limbs and the death of the children.

10. The defendant Pfizer, Inc. is one of the world's largest pharmaceutical companies and world premier research-based multinational pharmaceutical and health care company, a Delaware corporation with its corporate headquarters in New York City, but with its main headquarters for anti-infective clinical development at Pfizer's Global Research and Development World Headquarters, a division of Pfizer, Inc. in Groton and New London, Connecticut, and at the time of the incident in question, in. Groton, Connecticut..

11. In the middle of this outbreak of the cholera, meningitis and gastroenteritis defendant Pfizer, Inc. specially chartered a DC-9 airplane which upon reasonable belief and information was registered in the United States and, led by a six-person team of top-level Pfizer executives and/or scientists and/or doctors went to Kano, Nigeria between March, 1996 and/or April, 1996 to Kano's Infectious Disease Hospital to begin the testing of the children.

12. Instead of providing the children with safe and effective and proven therapy for these diseases, the defendant Pfizer, Inc. selected specific children, including the minor plaintiffs and had them

participate in a medical experiment of a new, untested and unproven drug without first obtaining their or their parents informed valid consent, not did they inform or sufficiently inform the children or their parents that Pfizer's proposed protocol and treatment was experimental and that the parents and the children could refuse it and in lieu thereof select a already proven safe and effective treatment for their diseases by a charitable medical group that was at KIDH at that time and place.

13. After the children were chosen, they were separated from their parents and split into two groups. The first group was given Trovafloxacin Mesylate, hereinafter referred to as Trovan, which at that time was an unproven drug to treat the diseases these children were suffering from and had never been tested on humans, nor had there been complete, sufficient animal testing. Moreover, Trovan was already known to have life-threatening side effects for children and adults. The other half of the group was intentionally low-dosed with an improperly administered control drug Ceftriaxone. The potential low-dosing resulted in the injuries and deaths among the control group and bolstered Pfizer's claim that Trovan was effective and/or more effective than the other similar drugs already on the international market.

14. The defendant Pfizer, Inc. is the world's largest pharmaceutical company and represents, markets and advertises itself under the slogan "committed to kids" indicated in their Statement of Missions and Values that they have one purpose, "restore health and hope through innovation...the fundamental reason for our existence is to innovate

and to help others. Our business decisions are governed by this purpose, and Pfizer's corporate decisions are based on our commitment to health care...." "We expect the highest possible standard of ethical conduct and honesty in all our behavior, our science and our business practice." Pfizer Global Research and Development website, 2000. "Our interdisciplinary teams work in parallel to insure the safety, effectiveness and affordability of drug candidates." Pfizer also notes that while it is trying to discover new drugs and working on a candidate that would be good for a safe, healthy, drug, "our toxicologists, biologists, chemists and others investigate its safety and toleration."

15. When the Pfizer team went to Kano, Nigeria to carry out the experiment there were efforts by Medecins Sans Frontieres (MSF), a recognized humanitarian relief organization also known as Doctors Without Borders which was already on the scene providing humanitarian relief. Whereas Pfizer took this opportunity to quickly conduct a test on the young children with the potentially dangerous antibiotic Trilovan, and as a result the minor plaintiffs were prevented from receiving adequate medical care and treatment and were injured, maimed or died.

16. Pfizer could expect to realize substantial financial benefits for its corporation from this experimental trial if successful results could be recorded and achieved.

17. In March, 1996 Pfizer's research team went to Kano, Nigeria and stayed approximately one month at the Infectious Disease Hospital selecting children it believed would be best for its own

purposes for the test results selecting them from the sick population at this unsanitary, non-modern hospital.

18. In conducting this Trovan Drug Test, Pfizer violated international law, federal regulations, principles of medical ethics and even back-dated necessary approvals.

19. Pfizer's violations referred to within this complaint including the failure to get a consent and/or informed consent before performing these medical experiments on the subject children was contrary to customary international law, the Nuremberg Code, The Declaration of Helinski and The International Covenant on Civil and Political Rights (hereinafter ICCPR).

20. Then Pfizer began conducting its largest drug testing program in clinical tests with regard to Trovan. Prior animal testing, had indicated that Trovan might cause significant adverse effects in children, such as joint disease, abnormal cartilage growth, and osteochondiosis disease which could further result in improper bone formation and/or liver damage.

21. Pfizer further violated international law by failing to inform the plaintiffs that there was an alternative to a treatment being provided by Pfizer and specifically, that MSF was on the IDH grounds where a team of medical personnel trained and experienced in epidemic relief work were treating similar pediatric meningitis patients with an internationally recommended drug for the safe treatment of bacterial meningitis. Thus while MSF and other organizations offered safe and effective

treatment for bacterial meningitis on the scene, Pfizer conducted a medical experiment that had been initiated, planned, developed, promulgated, manufactured, distributed, designed, formulated, prepared, assembled and researched in Connecticut at the Groton, Connecticut research facility involving the use and preparation for the drug trials relating to the antibiotic Trovan.

22. In addition to the other violations of international law and the Connecticut Unfair Trade Practices Act and the Connecticut Products Liability Act, Pfizer:

(a) failed to develop and adhere to an appropriate test protocol before children;

(b) failed to perform material diagnostic and evaluative testing to insure the children's selected for the Kano Trovan Test in fact were already suffered from a particular form of bacterial meningitis;

(c) failed to insure the test site had sufficient medical staff, proper equipment, materials and proper sanitation to safely and properly carry out the test;

(d) failed to stop and/or modify treatment for those treatment who did not improve after the initial course of therapy;

(e) failed to conduct any appropriate follow-up treatment or evaluation to determine what impact the Kano Trovan Test had on its participants and for those that survived to assess and re-evaluate in an attempt to ameliorate their medical condition.

23. At the time the test was carried out, a Pfizer employee and/or agent assigned to Kano and who had been part of the planning process in Connecticut with regard to the Trovan test, had repeatedly informed Pfizer senior management that the Kano Trovan Test was oppressive and inappropriate and illegal in nature of said test, a Pfizer employee and/or agent who was an infectious disease specialist assigned to the Kano Trovan Test and had repeatedly informed Pfizer's senior management before, during and after the execution of the test that the Kano Trovan Test was a violation of international law, federal regulations and medical ethical standards. Dr. Juan Walterspiel, a pediatric infectious disease specialist who was employed by Pfizer during the relevant time and oversaw the pediatric trials of Trovan filed a complaint in our Federal District Court of Connecticut on May 18, 1998 claiming that the test which was concocted in Connecticut was not only violative of international law, federal regulations and ethical medical standards but that the tests could result in life-threatening illness and disease to the children involved, such as the minor plaintiffs. Pfizer's violation of international law, State of Connecticut law and federal regulations caused the death of

many children including many of the plaintiffs cited herein and/or caused permanent deformities and/or injuries to three hundred thirty-seven other children including permanent physical and neurological damage such as paralysis, deafness and brain damage. With regard to the specific minor plaintiffs, many lost their sense of hearing, speech and sound and required the amputation of limbs. Many suffered psychological and emotional trauma and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities

24. Pfizer should have been aware that Trovan had the probable cause to produce significant adverse effects in children as there had been joint damage in animal studies as well as abnormal cartilage growth and osteochondiosis, all of which could cause defective bone formation and paralysis and/or partial crippling.

25. Pfizer also knew or should have known before the Trovan test that the use of Trovan had been correlated to liver toxicity and that there had been no safe dosage established. Therefore Pfizer knew that it would need extensive conclusive testing that would prove Trovan safe and effective in order to secure approval for Trovan to be used in children on the American and international markets.

20.[*] Dr. Scott Hopkins who was a doctor and researcher at the Groton, Connecticut headquarters of Pfizer, made the proposal to senior Pfizer

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[*] There are two sets of paragraphs numbered 20-25 in the original complaint.

executives to leave a six-person team to Kano, Nigeria. This plan was incubated, developed, proposed, administered, advertised and implemented from the Pfizer Central Global Research and Development World Headquarters on the Groton campus with two million square feet of laboratory space and over four thousand skilled research scientists, technicians, clinicians and professionals.

21. Pfizer then began the proposal for the Kano Trovan Test which if successful could reasonably lead to FDA approval for marketing of this drug to treat children all over the world as well the United States and projected total annual sales that could exceed one billion dollars. Prior to the Pfizer Kano Trovan Test only one child had ever been given Trovan because in that case all of their antibiotics had failed and even then at no time had a child ever been given an oral solution of Trovan. Pfizer then began to formulate its protocol in Connecticut for its Kano Trovan Test and did so in a uncharacteristically short time, six weeks, when usually protocols take a year or more to formulate. Pfizer then informed the FDA of its intent to conduct the study under the export waiver option. on March 15, 1996. This was because before Trovan could be utilized in Nigeria for clinical trials Pfizer needed to secure FDA authorization for export. Supposedly Pfizer had obtained the required letter of request from the Nigerian government and a March 28, 1996 letter by virtue of a IDH Ethics Committee permitting Pfizer to export Trovan to Kano. This in spite of the fact that both letters pre-date Pfizer's departure for Kano and that no IDH Ethics Committee existed as of March 28, 1996 and that the March 28, 1996 letter was back-dated in response

only to a 1997 FDA audit. Further, the Nigerian dictatorship at the time was intimately involved and contributed, aided, assisted and facilitated Pfizer's efforts to conduct the Trovan test, allowing, and arranging Pfizer's accommodations in Kano and further acted to silence Nigerian physicians who became critical of the company's test. Pfizer's main, if not sole, purpose for conducting these tests in Kano was to hasten the FDA approval of Trovan in the United States to treat pediatric patients. With the government of Nigeria's assistance Pfizer's team was given control of the IDH's wards to conduct the Kano Trovan Test.

22. Thereafter on or about April, 1996 Pfizer researchers from Connecticut utilizing and chartering a private DC-9 aircraft which on reasonable information and belief was registered in the United States and then flew to Kano, Nigeria's Infectious Disease Hospital and began the testing of Trovan on children in Nigeria, including the plaintiffs.

23. The testing consisted of three U.S. physicians who came from Connecticut and four indigenous Nigerian doctors.

24. Neither Pfizer nor any of its agents or employees:

(a) indicated to the plaintiffs or their guardians that they were offering an experimental treatment;

(b) provided any informed consent document to the plaintiffs and guardians to read and sign;

(c) informed the plaintiffs that they had the option of receiving alternate provable treatment provided by MSF.

25. The children treated by Pfizer were taken by the agents, servants or employees of the company isolated from their families in the IDH ward run and controlled by Pfizer, and the windows were covered and a screen erected to cut off any visibility from the outside world.

26. Pfizer conducted the tests on hundreds of Nigerian children, of which multiple children died who were given the drug Trovan and mutiple children who were in the control group also died who had been given inadequate doses of Ceftriaxone.

27. After only two weeks of compiling data, the Pfizer team left Nigeria and did not return nor did they provide any follow-up evaluation of the minor plaintiffs.

28. Pfizer's conduct in carrying out the Kano Trovan Testing constituted cruel, inhuman and degrading treatment and was immoral and/or unfair and/or deceptive and/or oppressive.

29. Even though Pfizer's own protocol directed that one-half the patients get Trovan and the other half receive an injection of Ceftriaxone, which is a drug manufactured by a competitor of Pfizer and which is and was an effective FDA approved meningitis drug for children. Pfizer did not administer the Ceftriaxone as recommended and purposely reduced the amount to one-third the recommended dosage.

30. Pfizer's protocol also dictated that the children involved in the testing were to have their blood tested on arrival and five days thereafter and that if the children's condition was not improving with Trovan, they were to be switched to Ceftriaxone. Pfizer deviated from its own protocol because it did not regularly analyze blood specimens from the patients and could not reasonably assess the patients' reaction to Trovan until such patients had exhibited specific observable permanent injuries. Moreover, the protocol required Pfizer to obtain signatures of witnesses attesting to the oral consent of the parents that chose to participate in the trial, and this form was never used.

31. Pfizer's protocol required that the patients be informed of their right to opt out of the study at any time and to be given the option of choosing alternative treatment, but Pfizer did not inform the plaintiffs that it was conducting an experimental drug test with regard to Trovan or that the alternative treatment was available right on site from MSF.

32. Pfizer violated international law and specifically:

(a) Principle 1 of the Nuremberg Code;

(b) Article 7 of the ICCPR; and

(c) FDA regulations

by failing to inform the plaintiffs of the possible effects on their health by participating in this experiment and more particularly, the risk of joint damage and liver damage which Pfizer knew or

reasonably should have known was associated with drugs such as Trovan and the further the risks associated with inadequate and/or low doses of Ceftriaxone.

33. Pfizer violated Principle 4 of the Nuremberg Code and the Declaration of Helsinki by failing to provide testing to evaluate joint and liver damage of the minor plaintiffs before, during and after the treatment where Pfizer had required MRI examinations by orthopedic specialists in trials of similar antibiotics in the United States. It did not do this evaluation of the Nigerian children enrolled in the experiment in Kano even though Pfizer noted that children who were given Trovan showed signs of joint pain at three times the rate of children who took the controlled drug. Pfizer violated the Declaration of Helsinki and FDA regulations by failing to have an IRB view and approve its experimental protocol even though Pfizer contends that it received approval for the Trovan test from the Nigerian government and from an ethics committee at Kano Hospital . This letter was back-dated. At the time its approval was allegedly granted the hospital had no ethics committee. Further such approval letter was not created until over a year later after an FDA audit in 1997.

34. Pfizer violated Principles 4, 5, 6 and 10 of the Nuremberg Code and the Declaration of Helsinki which prohibits the continuation of an experiment that will likely result in injury, and during the Kano Trovan Test Pfizer did not change the drug nor the dosage given to the children whose conditions had worsened and they also failed to administer sufficient Ceftriaxone in safe and effective amounts.

Pfizer violated Principles 4, 5, 6 and 10 of the Nuremberg Code and the Declaration of Helsinki by failing to provide alternative treatments to patients who did not respond to the drug administered and failing to provide all patients with the best proven diagnostic and therapeutic methods relative to treating bacterial meningitis nor did they use the drug recommended by the World Health Organization for treatment of epidemic bacterial meningitis, the chloramphenicol.

35. Pfizer violated Principle 1 of the Nuremberg Code and Declaration of Helsinki by:

(a) failing to design and conform the Kano Trovan Test to clearly form related experimental protocol in compliance with generally accepted scientific principles;

(b) failing to secure guidance on such protocol from an independent review;

(c) conducting the Kano Trovan Test in an inadequate facility which lacked proper sanitation, electricity and medical supplies and proper and appropriate equipment;;

(d) carrying out the experiment with improperly trained, inexperienced and inadequate staff.

36. Pfizer violated Article 7 of the ICCPR, the Nuremberg Code and the Declaration of Helsinki

by subjecting the plaintiffs to cruel and/or inhuman treatment by:

(a) administering painful medical treatments without first obtaining consent

(b) administering and significantly reducing the recommended dosage of Ceftriaxone to the patients in the control group thus not healing their disease;

(c) administering Trovan, a drug known to cause liver damage and joint problems to children without disclosing the risks of such exposure;

(d) failing to conduct adequate follow-up examinations to determine the injuries caused by the Kano Trovan Test and the possibility of correcting those problems or ameliorating them for the children who survived.

37. Pfizer violated Principle 3 of the Nuremberg Code and Declaration of Helsinki by failing to have sufficient documentation or knowledge or confirmation relating to the history of the specific strain of bacterial meningitis present in Kano prior to undertaking the Kano Trovan Test.

38. Pfizer's own pediatric infectious disease specialist who was intimately involved in the preparation and formulation and implementation of Kano Trovan Test and oversaw the trials, Dr. Juan

Walterspiel filed a complaint in our Federal Court in this District of Connecticut on May 18, 1998. Walterspiel v. Pfizer, Inc., 98 CV 917 (JCH) wherein Dr. Walterspiel alleged that he informed Pfizer's senior management on numerous occasions before, during and after the Kano Trovan Test that, inter alia:

(a) the experiment was violative of international law, federal regulations and ethical standards;

(b) Pfizer's methods could result in life-threatening illnesses and deaths to the children enrolled;

(c) Pfizer failed to obtain proper informed consent;

(d) Pfizer failed to provide adequate follow-up care;

(e) Pfizer failed to conduct proper initial screening tests;

(f) Pfizer failed to screen patients for kidney failure and hemolylitlc anemia;

(g) Pfizer had to utilize inexperienced staff;

(h) Pfizer failed to provide active patient care;

(i) He believed there was a conflict of interest to allow Pfizer officials to actually participate in the trials themselves;

(j) Oral formulation of Trovan had never been given to children before or, at best, only one child;

(k) Some of the children in the test were in critical condition and most of them malnourished, which made oral absorption unpredictable;

(l) A strain of the infection that caused the epidemic was not tested for its sensitivity before the test was conducted;

(m) These type of drugs are known to cause joint problems;

(n) Inexperienced staff in that scores were reversed;

(o) Lack of experience in pediatric joint evaluation;

(p) Lack of experience in blood drawing;

(q) Inexperience in placing IV lines;

(r) Insufficient facilities;

(s) He believed improper research methods allowed Nigerian children to die unnecessarily in violation of standards and protocols which governed such testing;

(t) Improper and unsafe methods were being utilized in testing Trovan on Nigerian children and

that these methods would result in life-threatening illnesses and deaths to these children;

(u) He further alleged a personal relationship between two Pfizer researchers, one supervising the other, both involved in the Trovan study, was an improper relationship potentially affecting these clinical studies of the Nigerian children;

(v) 21 C.F.R. §50, et seq. required proper informed consent of a child's parent or guardian before drugs could be tested on human subjects;

(w) 21 C.F.R. §312.120 incorporates the international agreement known as the Declaration of Helsinki at the foreign clinical studies such as that conducted in Nigeria and that studies were in violation of the Declaration of Helsinki;

(x) There was a failure to disclose all relevant information regarding the Trovan Drug Study to the FDA.

39. These criticisms by Dr. Walterspiel charged that Pfizer violated the Nuremberg Treaty, Article 7 of the ICCPR and the Declaration of Helsinki. Dr. Walterspiel was fired by Pfizer, for which Dr. Walterspiel filed the complaint alleging

retaliation for whistle-blowing, specifically related to the Kano Trovan Test.

40. Dr. Amir Imam Yola, a Nigerian physician involved in the Kano Trovan Test, thought that the test was "a bad thing, but he did not object because the test seemed to have the backing of the Nigerian government and he was fearful to protest due to the difference between the system in America and Nigeria.

41. Pfizer with regard to the Kano Trovan drug test violated the Nuremberg Code, Principle 1, which calls for voluntary consent being absolutely essential and the person giving the consent should have the legal capacity to do so without the intervention of fraud, deceit, duress, overreaching or other ulterior forms of constraint or coercion. The duty and responsibility for ascertaining the quality of consent rests upon the individual who initiates, directs or engages in the experiment.

42. Pfizer with regard to the Kano Trovan drug test violated Principle 4 of the Nuremberg Code which states that the experiment should be conducted to avoid all unnecessary physical and mental suffering and injury.

43. Pfizer with regard to the Kano Trovan drug test violated Principle 5 of the Nuremberg Code which states that no experiment should be conducted where there is a...reason to believe that death or disabling injury will occur.

44. Pfizer with regard to the Kano Trovan drug test violated Principle 7 of the Nuremberg Code which states that proper precautions should be taken and adequate facilities provided to protect the

experimental subjects against injury, disability or death.

45. Pfizer with regard to the Kano Trovan drug test violated Principle 9 of the Nuremberg Code which notes that the subject should be able to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

46. Pfizer with regard to the Kano Trovan Drug Test violated Principle 10 of the Nuremberg Code which indicates that the scientists in charge of the experiment must be prepared to terminate the experiment at any stage if he has probable cause to believe in the exercise of good faith, superior skill and careful judgment that the continuation of the experiment is likely to result in injury, disability or death of the experimental subject.

47. Pfizer with regard to the Kano Trovan Drug Test violated the ICCPR, a treaty to which the United States is a party, Article 7 finds that "no one should be subject to torture, cruel, inhuman or degrading treatment...In particular no one shall be subject without his free consent to medical or scientific experimentation."

48. Pfizer with regard to the Kano Trovan Drug Test also violated the Universal Declaration of Human Rights, Article 5, which says that "no one shall be subject to torture or cruel, inhuman or degrading treatment..."

49. Pfizer with regard to the Kano Trovan Drug Test also violated the Declaration of Helsinki which forbids non-consensual medical experimentation;

(1) Based on adequately performed laboratory and animal experimentation;

(2) Design and performance of each experimental procedure involving human subjects should be clearly formulated in experimental protocol which should be transmitted to a specially appointed independent committee for consideration, comment and guidance;

(3) Biomedical research involving human subjects cannot be carried out unless the importance of the objective is in proportion to the inherent risk;

(4) Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be preventable;

(5) In any research on human beings each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail;

(6) The potential benefits, hazards and discomforts of a new method should be weighed against the advantages of the best current

diagnostic and therapeutic method;

(7) In any medical study every patient including those of a control group should be assured of the best proven diagnostic and therapeutic methods.

50. Pfizer with regard to its conduct of the Kano Trovan drug test violated the International Ethical Guidelines for Research Involving Human Subjects known as the CIOMS Guidelines which were promulgated to enunciate the ethical principles embodied in the Nuremberg Code, Article 7 of the ICCPR and the Declaration of Helsinki and how they can be accommodated nuances of developing countries.

51. Pfizer with regard to its conduct of the Kano Trovan Drug Test violated Guideline 2 which indicates that the experimental subject must be given the following information in a language that he or she is capable of understanding: the aims and methods of research, the benefits that might reasonably be expected to result, the foreseeable risks, the discomfort to the subject, alternative procedures, a course of treatment that might be as advantageous, that the individual's freedom to refuse to participate will be free to withdraw from research at any time and whether or not the subject or the subject's family or dependents will be compensated for disability or death resulting from such injury.

52. Pfizer with regard to its conduct of the Kano Trovan drug test violated Guideline 5 of the CIOMS, "Research Involving Children", which

requires that before undertaking research involving children that:

(a) Consent has been obtained;

(b) The test is intended to provide therapeutic benefit or likely to be at least as advantageous to the individual child subject as any available alternative. As the commentary of the Guidelines indicate, older children who are capable of informed consent should be selected before younger children or infants.

53. Pfizer with regard to its conduct of the Kano Trovan drug test violated Guideline 8 of the CIOMS regarding "Research Involving Subjects in Undeveloped Countries" which requires that "the research is responsive to the health needs and priorities of the community in which it is to be carried out and the proposals for research have been reviewed and approved by an ethical review committee." The commentary on Guideline 8 amplifies the concept that many people are incapable of informed consent because they are illiterate or unfamiliar with the concepts of medicine in undeveloping countries that certain testers may wish to take advantage of that fact. Most developing countries have well-developed regulations and ethical review committees which could have the effect of delaying access to research subjects. Others may find it less expensive to conduct in developing countries research that is designed to develop drugs and other products for market in developing countries. Commentary relating to Guideline 8 also

notes informed consent requires under Guidelines 1 and 3 the subject must be clearly told they are participation is entirely voluntary and that they can withdraw at any time.

54. Guideline 13 requires that research subjects who suffer physical injury as a result of their participation are entitled to such financial or other assistance as would compensate them equitably for any temporary or permanent impairment or disability. In the case of death their dependents are entitled to material compensation. The right to compensation may not be waived. The Commentary notes that the sponsor, whether a pharmaceutical company, a government...should agree before the research begins to provide compensation.

55. Guideline 14 advises that all proposals to conduct research involving human subjects must be submitted to review and approval to one or more independent ethical and scientific review committees. The investigator must obtain such approval of the proposal to conduct research before the research has begun, which in turn Commentary to Guideline 14 references, the Declaration of Helsinki, Article II, 3 notes that every patient including those of a control group should be assured of the best proven diagnostic and therapeutic method. Additionally stressing the need for particularly stringent review requirements in the case of proposed research involving children and/or communities unfamiliar with modem clinical concepts and that the investigator should provide information showing:

(a) A clear understanding of the research objectives;

(b) Precise description of all interventions including intended dosages of drugs and planned duration of treatment and description of plans to withdraw or withhold standard therapy;

(c) Anticipated benefits and risk of participation;

(d) Means proposed to obtain individual informed consent;

(e) The rights and welfare of the subjects will be adequately protected;

(f) Identification of the organization sponsoring the research and a detailed account of the sponsor's financial commitment to the research institution, investigators or community;

(g) Plans to inform subject about harms and benefits during the study;

(h) The results of the study at its conclusion; and

(i) That the principles of the Declaration of Helsinki will be implemented.

56. Guideline 15 notes that the externally sponsored research country has ethical obligations to

submit the research protocol to the ethical and scientific review according to the standards of the country of the sponsoring agency and that those standards should be no less exacting than they will be in the case of research carried out in that country.,

57. The Commentary to Guideline 15 also echoes Guideline 13 by saying that sponsors have an obligation to insure that subjects who suffer injury as a consequence of research an1d that compensation should be provided for death or disability occurring as a consequence of such injury and that sponsors are inspected to insure their research subjects and the communities from which they are recruited are not made worse off as a result of the research.

58. The ICCPR requires each state party to provide victims of testing abuse an "effective remedy". ICCPR at 2(3)A.

59 United Nations Universal Declaration of Human Rights in Article 8 supplements this by stating that "everyone has an underlying right to an effective remedy by the competent national tribunal for acts violating one's fundamental rights. (Writer's emphasis added.) It also recognizes that the remedy must be adjudicatory and that it guarantees the victim of human rights abuses his or her day in court. As stated within this complaint, the plaintiffs hereby allege that they cannot find in the forum of the Country of Nigeria a truly adjudicatory forum that would guarantee them the human rights abuses that they allegedly suffered and that they will have their day in court without interminable delay. In the instant matter the Nigerian government acted in concert with Pfizer by providing a letter requesting

the FDA to authorize the export of Trovan to Nigeria and arranging for Pfizer's accommodations at the IDH, assigning Nigerian physicians to assist in the project, back-dating an approval letter that international protocol required to be ascertained prior to the test and acting to silence the Nigerian physicians critical of the company's test. Thus the Nigerian government and Pfizer were joint participants in the Trovan drug test treatment case involving the instant plaintiffs was filed. These plaintiffs had filed a law suit relating to the Trovan drug test in the Federal High Court in Kano in Nigeria. The Presiding Judge of the Federal High Court in Kano, Nigeria, of which there are only two sitting judges, was removed for corruption which caused a six-month period of inactivity in the lawsuit filed by the instant plaintiffs in Nigeria from November, 2001 through April, 2002. When the second judge in the Federal High Court in Kano State temporarily took over the jurisdiction, but thereafter the Judge who handled the case only for a period of April, 2002 though July, 2002 delivered an initial ruling in the case and afterwards in open court declined jurisdiction claiming that he had to do so for personal reasons which have still not been described or disclosed. The Nigerian Judiciary had not posted any other judge to the Federal High Court since October, 2001 to the present date and the case was suffering an indefinite adjournment which is causing undue prejudice to those plaintiffs who are still alive and suffering from continuing and permanent physical deformities caused by the defendant. Thus the plaintiffs through their Nigerian counsel discontinued their suit in the Nigerian court for want of diligent prosecution by the Nigerian

courts and filed a Notice of Discontinuance on October 17, 2002. Thus the case brought by these very plaintiffs in the instant matter of our District Court of Connecticut found that justice had been delayed and now denied in Nigeria. The Nigerian Court has by its action and non-action declined to presently accept jurisdiction of this case involving the instant plaintiffs. It is alleged that the, defendant Pfizer, Inc. may have acted in concert with the Nigerian government and the Nigerian government approved the study and was involved in the back-dating of the Ethics Committee letter, and silenced the testing of Nigerian doctors relating to the Trovan drug study. Further, the Nigerian government

(a) has been described as akin to civilian dictatorship;

(b) the legislature has moved to impeach the President of Nigeria on three attempts within the last three years;

(c) the Nigerian government is only allowed three elections by a civilian government since Nigerian's independence in 1960, two of those elections in 1964 and 1988 were considered corrupted and led to military coups;

(d) the number one law officer, Attorney General Chief Bola Inge was murdered on October 23, 2001, Whose murder is still unsolved;

(e) There exists in Nigeria, particularly in northern Nigeria where Kano is located, the Sharia legal system which now exists in conjunction with the court system. This was demonstrated very recently in the rioting related to the Miss World competition which actually had to leave Nigeria due to complaints by the Sharia legal system.

(f) Also, in the near recent past, several judges have been indicted on charges of abuse of power and mal-administration.

All this taken singularly or in combination leaves the Nigerian lawyers to believe that the Nigerian court system, in light of all the aforementioned and because the Nigerian government allegedly acted in concert with Pfizer, will not provide a fair and adequate remedy for the Nigerian plaintiffs and thus may not be the appropriate forum for justice to be dispensed in this case.

60. The FDA can accept and validate clinical studies conducted outside the United States in relation to testing of the safety and efficacy claims for drugs but they normally have to be conducted under Investigational New Drug Exemption (IND) as governed by the FDA under its informed consent and Institutional Review Board (IRB) requirements. 21 C.F.C.F.R §312.

61. However, all foreign clinical trials must conform to the standards of good clinical practice, and the FDA has defined the required elements of conformed consent which require a statement indicating the type of research, an explanation for the purposes, his expected duration, description of the procedures to be followed and identification of any procedures which are experimental.

62. Description of any reasonably foreseeable risks or discomforts to the subject, and disclosure of appropriate alternative procedures or course of treatment which might be advantageous to the subject. For research involving more than a minimal risk, an explanation as to whether any compensation or medical treatments are available if the injury occurs. The subject may discontinue participation at any time without penalty or loss to the benefits. The FDA regulations require that informed consent be documented in writing in a form approved by the IRB.

63. FDA Regulations require further protection with regard to children involved in clinical studies. When there is greater than minimal risk to children, one must show the benefits to the individual subjects and that the risks must be justified by the anticipated benefits to subjects. In relation the anticipated benefit must be as favorable as available alternative approaches and provisions must be made for securing the consent of the children, permission of the parents or guardians and that that consent should allow the consentee to consider whether or not to participate and to minimize the possibility of coercion or undue influence in that the consent should be in a language

understandable to the subject, (21 C.F.C.F.R. §50-.20) and that to avoid a conflict of interest the FDA Regulations prohibit any member of a clinical investigation team from participating in an IRB review and that any proposed change that is not dimittimus anything that would increase risk or discomfort, the IRB must review and approve the proposed change before it can be implemented.

64. Pfizer's Kano Trovan Drug Testing was subject to FDA regulations because the FDA regulations are expressly incorporated by the CIOMS Guidelines. The Declaration of Helsinki, the Nuremberg Code, Article VII of the ICCBR, the CIOMS Guidelines and the FDA regulations set forth at least the minimum United States and international standards of medical research and drug studies and tests on human subjects and constitute international customary law, norms of international law or law of nations requires that no medical experimentation be allowed on humans without their consent

65. Good clinical practice mandates that the subjects should have a complete history, physical examination at the beginning of the process in order to confirm the diagnosis under study and to rule out a differential diagnosis.

66. In order to determine and diagnose bacterial meningitis the standard of care requires that a central spinal fluid analysis be taken or a lumbar puncture and in addition specific blood tests tailored to the diagnosis of bacterial meningitis.

67. Exclusion criteria should be used to exclude patients would be:

(a) excluding those patients who have the disease;

(b) those patients whose disease has reached the stage where drug intervention would not be efficacious;

(c) exclude patients who have potentially unacceptable risk of adverse effects;

(d) exclude patients with a severe underlying disease unrelated to the disease that is the focal point of the study.

68. In foreign clinical studies involving bacterial meningitis, the standard of care should be the same if not similar to that in the United States and in the State of Connecticut would not include conducting an experiment where there is not sufficient facilities and sufficient hygienic conditions and sufficient equipment and staff.

69. The standard of care also would require a second central spinal fluid analysis after the treatment begins to calculate whether the patient is responding to said treatment and the standard of care would exclude conducting bacterial meningitis experiments during an epidemic and would also require follow-up assessment of the patients' physical status including physical, neurological and audiological evaluation which should be obtained approximately six weeks after the study is completed and then again approximately six months or more after that.

## IV. PLAINTIFFS' INJURIES WERE PROXIMATELY CAUSED AND/OR A SUBSTANTIAL FACTOR BY PFIZER'S KANO TROVAN TEST

70. Because of Pfizer's actions described more fully within this complaint including given an unproven oral suspension or tablet form of Trovan to critically ill Nigerian children who presumably had bacterial meningitis when there was an availability of alternative drugs that were safe and effective or the children in the control group were given inadequate doses of Ceftriaxone which would not allow the drug to work effectively. Some of the plaintiffs died but not before suffering with various maladies as stated within caused by the administration of Trovan or the low dosage of Ceftriaxone. The remaining plaintiffs who did not die also suffered various maladies, including loss of hearing, loss of sight, brain damage, joint damage, amputation of limbs, paralysis, depression, psychological and emotional trauma and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities. As described hereunder, the following children were each entered into the Kano Trovan Test and suffered the specific injuries as a result thereto:

71. Yahaya Ismaica was a fifteen (15) year-old male whose guardian was Ajudu Ismaila Adamu. He was brought by, his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon, he

was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Yahaya Ismaica to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Yahaya Ismaica and his family informed that there were safe and effective alternative treatments at IDH.

72. Neither Yahaya Ismaica nor his parents were informed that Pfizer was offering experimental treatment nor did they consent to the treatment and Yashama Ismaica suffered injuries including depression, joint pains, loss of hearing and had brain damage, and psychological and emotional trauma, including branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

73. As a result of their injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

74. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of his life.

75. Bashir Mohamed was a five (5) year-old male whose guardian was Malam Mohamed. He was brought by his parents to the IDH Hospital to seek

treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Bashir Mohamed to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Bashir Mohamed and his family informed that there were safe and effective alternative treatments at IDH.,

76. Neither Bashir Mohamed nor his parents were informed that Pfizer was offering experimental treatment or consent to any such treatment and Bashir Mohamed suffered injuries including joint pains, chest pains, injury to joints and chest., psychological and emotional trauma.

77. As a result of their injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

78. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of his life.

79. Suyudi Yusuf was a twelve (12) year-old male whose guardian was Malam Yusub Ya'n Amale.

He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Suyudi Yusuf to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Suyudi Yusuf and his family informed that there were safe and effective alternative treatments at IDH.

80. Neither Suyudi Yusuf nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Suyudi Yusuf suffered injuries including deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

81. As a result of their injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

82. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of his life.

83. Nurudini Kwakaawa was a one (1) year-old male whose guardian was Malam Dauda Zango Kwajalawa. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Nurudini Kwakaawa to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Nurudini Kwakaawa and his family informed that there were safe and effective alternative treatments at IDH.

84. Neither Nurudini Kwakaawa nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Nurudini Kwakaawa suffered injuries including complete loss of hearing, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

85. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

86. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the

activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of his life.

87. Muh'd Tasiu Haruna was a four (4) year-old male whose guardian was Malam Haruna Adamu. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Muh'd Tasiu Haruna to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Muh'd Tasiu Haruna and his family informed that there were safe and effective alternative treatments at IDH.

88. Neither Muh'd Tasiu Haruna nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Muh'd Tasiu Haruna suffered injuries including complete loss of hearing, loss of speech, brain damage, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

89. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

90. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of his life.

91. Rabi Dahiru was a three (3) year-old female whose guardian was Malam Dahiru Ya'u. She was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Rabi Dahiru to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Rabi Dahiru and her family informed that there were safe and effective alternative treatments at IDH.

92. Neither Rabi Dahiru nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Rabi Dahiru suffered injuries including complete loss of hearing, loss of speech, brain damage, psychological and emotional trauma, and branding with the

acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

93. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

94. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of her life.

95. Zainab Musa Dahuru was a fifteen (15) year-old female whose guardian was Malam Dahuru Ya'y. She was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Zainab Musa Dahuru to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Zainab Musa Dahuru and her family informed that there were safe and effective alternative treatments at IDH.

96. Neither Zainab Musa Dahuru nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Zainab Musa Dahuru suffered injuries including partial loss of hearing, frequent fevers, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, and a presently undiagnosed permanent condition.

97. As a result of her injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

98. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of her life.

99. Ismaila Musa was a twelve (12) year-old male whose guardian was Malam Musas Zangon Marikita. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Ismaila Musa to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion

about the Kano Trovan Test or seek their informed consent for his participation in the experiment nor was Ismaila Musa and his family informed that there were safe and effective alternative treatments at IDH.

100. Neither Ismaila Musa nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Ismaila Musa suffered injuries including complete loss of hearing, loss of speech, brain damage, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

101. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

102. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of his life.

103. Hamza Alhaji Muhammed was a six (6) year-old male whose guardian was Arhaji Muhammad Soja. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano

Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Hamza Achaji Muhammed to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Hamza Achaji Muhammed and his family informed that there were safe and effective alternative treatments at IDH.

104. Neither Hamza Achaji Muhammed nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Hamza Achaji Muhammed suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

105. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

106. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

107. Abdullahi Ibrahim was a thirteen (13) month-old male whose guardian was Achaji Ibrahim Dankwalba. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting

that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Abdullahi Ibrahim to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Abdullahi Ibrahim and his family informed that there were safe and effective alternative treatments at IDH.

108. Neither Abdullahi Ibrah'm nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Abdullahi Ibrahim suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurrna", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

109. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

110. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

111. Jamilu Lawan was a two (2) year-old male whose guardian was Malam Lawan Dan Zaria. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Jamilu Lawan to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Jamilu Lawan and his family informed that there were safe and effective alternative treatments at IDH.

112. Neither Jamilu Lawan nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Jamilu Lawan suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

113. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

114. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the

injury and his ability to get around and enjoy life's offerings has been vitiated.

115. Ummi Alhaji Muhammed was a seven (7) year-old female whose guardian was Alhaji Muhammed Soja. She was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Ummi Alhaji Muhammed to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Ummi Alhaji Muhammed and her family informed that there were safe and effective alternative treatments at IDH.

116. Neither Ummi Alhaji Muhammed nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Ummi Alhaji Muhammed suffered injuries including deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, the apprehension of death and death itself in 2000 due to the negligence of the

defendant Pfizer, Inc. and before that time had a poor sense of hearing.

117. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

118. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

119. Mustapha Zubairu was a ten (10) year-old male whose guardian was Ismaila Zubairui. He was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Mustapha Zubairu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Mustapha Zubairu and his family informed that there were safe and effective alternative treatments at IDH.

120. Neither Mustapha Zubairu nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Mustapha Zubairu suffered injuries including

deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

121. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

122. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

123. Habiba Lawan was a five (5) year-old female whose guardian was Malam Lawan. Habiba Lawan was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Hasbiba Lawan to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Habiba Lawan and her family informed that there were safe and effective alternative treatments at IDH.

124. Neither Habiba Lawan nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Habiba Lawan suffered injuries including deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

125. As a result of her injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

126. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been impaired and will be so affected for the remainder of her life.

127. Sa'adatu Musa was a five (5) year-old female whose guardian was Abubakar Musa was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon Sa'adatu Musa was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Sa'adatu Musa to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral, assertion about the Kano. Trovan Test or seek their informed consent for his participation in the experiment, nor

was Sa'adatu Musa and her family informed that there were safe and effective alternative treatments at IDH.

128. Neither Sa'adatu Musa nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Sa'adatu Musa suffered injuries including severe chest and joint pains, psychological and emotional trauma.

129. As a result of her injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

130. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been impaired and will be so affected for the remainder of her life.

131. Haruna Abdu was a seventeen (17) year-old male whose guardian was Mohamed Abdu. Haruna Abdu was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Haruna Abdu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed

consent for his participation in the experiment, nor was Haruna Abdu and his family informed that there were safe and effective alternative treatments at IDH.

132. Neither Haruna Abdu nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Haruna Abdu suffered injuries including blindness and severe joint pains, psychological and emotional trauma.

133. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

134. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be so impaired for the rest of his life.

135. Hajaran Hassan was a three (3) year-old female whose guardian was Mallam Hassan. Hajaran Hassan was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Hajaran Hassan to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through

a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Hajaran Hassan and her family informed that there were safe and effective alternative treatments at IDH.

136. Neither Hajaran Hassan nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Hajaran Hassan suffered injuries including frequent fever, joint pains, deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

137. As a result of her injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

138. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been impaired and will be so impaired in the future..

139. Auwalu Mohamadu Jabbo was an eight (8) year-old male whose guardian was Mallam Mohamadu Jabbo. Auwalu Mohamadu Jabbo was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the

Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Auwalu Mohamadu Jabbo to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Auwalu Mohamadu Jabbo and his family informed that there were safe and effective alternative treatments at IDH.

140. Neither Auwalu Mohamadu Jabbo nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Auwalu Mohamadu Jabbo suffered injuries including deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

141. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

142. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be impaired for the rest of his life.

143. Abubakar Yakubu was a six (6) year-old male whose guardian was Mallam Yakubu Umar. Abubakar Yakubu was brought by his parents to the IDH Hospital to seek treatment and while awaiting

that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Abubakar Yakubu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Abubakar Yakubu and his family informed that there were safe and effective alternative treatments at IDH.

144. Neither Abubakar Yakubu nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Abubakar Yakubu suffered injuries including deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

145. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

146. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be so impaired in the future..

147. Adamu Samaila was a six (6) year-old male whose guardian was Mallam Samaila. Adamu Samaila was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Adamu Samaila to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Adamu Samaila and his family informed that there were safe and effective alternative treatments at IDH.

148. Neither Adamu Samaila nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Adamu Samaila suffered injuries including deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

149. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

150. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the

injury and his ability to get around and enjoy life's offerings has been impaired and will be so impaired in the future.

151. Ukhasa Musa was a six (6) month-old male whose guardian was Musa Yahaya. Ukhasa Musa was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Ukhasa Musa to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Ukhasa Musa and his family informed that there were safe and effective alternative treatments at IDH.

152. Neither Ukhasa Musa nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Ukhasa Musa suffered injuries including deafness, loss of speech, severe joint pains, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

153. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

154. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be so impaired in the future.

155. Yashaya Samaila was a nine (9) year-old male whose guardian was Audu Ismaila Adamu. Yashaya Samaila was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without family's full consent or knowledge. Apparently Pfizer did not, conduct sufficient testing on Yashaya Samaila to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Yashaya Samaila and his family informed that there were safe and effective alternative treatments at IDH.

156. Neither Yashaya Samaila nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Yashaya Samaila suffered injuries including depression, joint pains, deafness and loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

157. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

158. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be so impaired in the future..

159. Zainabu Musa was a nine (9) year-old female whose guardian was Malam Musa Dahiru. Zainabu Musa was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Zainabu Musa to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about, the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Zainabu Musa and her family informed that there were safe and effective alternative treatments at IDH.

160. Neither Zainabu Musa nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Zainabu Musa suffered injuries including deafness, frequent fever and joint pains, psychological and emotional

trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities

161. As a result of her injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

162. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her. ability, to get around and enjoy life's offerings has been impaired and will be so impaired in the future..

163. Samaila Musa was a six (6) year-old male whose guardian was Malam Musa Zango. Samaila Musa was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Samaila Musa to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Samaila Musa and his family informed that there were safe and effective alternative treatments at IDH.

164. Neither Samaila Musa nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Samaila Musa suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

165. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

166. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be further impaired in the future.

167. Najib Maihula was a two (2) year-old male whose guardian was Mallam Alhassan Maihula. Najib Maihula was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Najib Maihula to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his

participation in the experiment, nor was Najib Maihula and his family informed that there were safe andd effective alternative treatments at IDH.

168. Neither Najib Maihula nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Najib Maihula suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

169. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

170. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be further impaired in the future.

171. Dankurma Gama was a two (2) year-old male whose guardian was Mallam Yusus Gama. Dankurma Gama was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Dankurma Gama to accurately diagnose bacterial meningitis,

nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment; nor was Dankurma Gama and his family informed that there were safe and effective alternative treatments at IDH.

172. Neither Dankurma Gama nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Dankurma Gama suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities.

173. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

174. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been impaired and will be further impaired in the future..

175. Abdullah Adamu was a three (3) year-old male whose guardian was Mallam Abdullah Adamu. Abdullah Adamu was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken

away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Abdullah Adamu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the, experiment, nor was Abdullah Adamu and his family informed that there were safe and effective alternative treatments at IDH.

176. Neither Abdullah Adamu noir his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Abdullah Adamu suffered injuries including severe joint pains and chest pain, psychological and emotional trauma, apprehension of death and death itself.

177. As a result of his injuries the minor plaintiffs earning capacity as well as future earning capacity is permanently impaired.

178. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

179. Hamisu Nuhu was a six (6) year-old male whose guardian was Dauda Nuhu. Hamisu Nuhu was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the

other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Hamisu Nuhu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Hamisu Nuhu and his family informed that there were safe and effective alternative treatments at IDH.

180. Neither Hamisu Nuhu nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Hamisu Nuhu suffered joint pains and severe chest pains, psychological and emotional trauma, apprehension of death and death itself.

181. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

182. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

183. Najaratu Abdullahi was a three (3) year-old female whose guardian was Mallam Abdullahi. Najaratu Abdullahi was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the

defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Najaratu Abdullahi to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Najaratu Abdullahi and her family informed that there were safe and effective alternative treatments at IDH.

184. Neither Najaratu Abdullahi nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Najaratu Abdullahi suffered injuries including joint pain and severe chest pain, psychological and emotional trauma, apprehension of death and death itself.

185. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

186. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

187. Sule Mohammed was an eight (8) year-old male whose guardian was Malam Umaru

Mohammed. Sule Mohammed was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon Sule Mohammed was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Sule Mohammed to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Sule Mohammed and his family informed that there were safe and effective alternative treatments at IDH.

188. Neither Sule Mohammed nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Sule Mohammed suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

189. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

190. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the

injury and his ability to get around and enjoy life's offerings has been vitiated.

191. Yusif Nasiru was a three (3) year-old male whose guardian was Mallam Nasiru. Yusif Nasiru was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Yusif Nasiru to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Yusif Nasiru and his family informed that there were safe and effective alternative treatments at IDH.

192. Neither Yusif Nasiru nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Yusif Nasiru suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

193. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

194. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

195. Nura Mohammed was a nine (9) year-old male whose guardian was Malam Hasan. Nura Mohammed was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Nura Mohammed to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Nura Mohammed and his family informed that there were safe and effective alternative treatments at IDH.

196. Neither Nura Mohammed nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Nura Mohammed suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian

northern communities, apprehension of death and death itself.

197. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

198. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

199. Sadiya Hassan was a one and one-half (1-1/2) year-old female whose guardian was Malam Hassan. Sadiya Hassan was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Sadiya Hassan to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Sadiya Hassan and her family informed that there were safe and effective alternative treatments at IDH.

200. Neither Sadiya Hassan nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Sadiya

Hassan suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

201. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

202. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

203. Aisha Lawan was a three (3) year-old female whose guardian was mallam lawan rijiyar Lemo. Aisha Lawan was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Aisha Lawan to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Aisha Lawan and her family informed that there were safe and effective alternative treatments at IDH.

204. Neither Aisha Lawan nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Aisha Lawan suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

205. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

206. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

207. Nafisatu Musa was a three (3) year-old female whose guardian was Yusuf Musa. Nafisatu Musa was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Nafisatu Musa to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor

was Nafisatu Musa and her family informed that there were safe and effective alternative treatments at IDH.

208. Neither Nafisatu Musa nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Nafisatu Musa suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

209. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

210. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

211. Umaru Muritala was a thirteen (13) year-old male whose guardian was Mallam Muritala. Umaru Muritala was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Umaru Muritala to accurately diagnose bacterial meningitis, nor did

they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Umaru Muritala and his family informed that there were safe and effective alternative treatments at IDH.

212. Neither Umaru Muritala nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Umaru Muritala suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

213. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

214. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

215. Madina Tanko was a seven (7) month-old male whose guardian was Mallam Tanko. Madina Tanko was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled

by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Madina Tanko to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Madina Tanko and his family informed that there were safe and effective alternative treatments at IDH.

216. Neither Madina Tanko nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Madina Tanko suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

217. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

218. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

219. Aisha Sheu was a four (4) year-old male whose guardian was Mallam Sheu. Aisha Sheu was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people

who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Aisha Sheu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Aisha Sheu and his family informed that there were safe and effective alternative treatments at IDH.

220. Neither Aisha Sheu nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Aisha Sheu suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

221. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

222. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

223. Kabiru Mohamed was a six (6) year-old male whose guardian was Malam Kabiru Mohamed Kabiru Mohamed was brought by his parents to the

IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Kabiru Mohamed to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Kabiru Mohamed and his family informed that there were safe and effective alternative treatments at IDH.

224. Neither Kabiru Mohamed nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Kabiru Mohamed suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", 'which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

225. As a result of his injuries the minor plaintiff's earning capacity as well as uture earning capacity is permanently impaired.

226. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

227. Rukiya Abdullahi was a three (3) year-old female whose guardian was Mallam Abdullahi. Rukiya Abdullahi was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Rukiya Abdullahi to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Rukiya Abdullahi and her family informed that there were safe and effective alternative treatments at IDH.

228. Neither Rukiya Abdullahi and her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Rukiya Abdullahi suffered injuries including deafness, blindness, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

229. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

230. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury, and her ability to get around and enjoy life's offerings has been vitiated.

231. Fatima Abubakar was a eight (8) year-old female whose guardian was Mallam Sule Abubakar. Fatima Abubakar was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Fatima Abubakar to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Fatima Abubakar and her family informed that there were safe and effective alternative treatments at IDH.

232. Neither Fatima Abubakar nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Fatima Abubakar suffered injuries including deafness, loss of speech, amputation of limbs, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian

northern communities, apprehension of death and death itself.

233. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

234. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

235. Baba Idris was a two (2) year-old male whose guardian was Mallam Idris. Baba Idris was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Baba Idris to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was and his family informed that there were safe and effective alternative treatments at IDH.

236. Neither Baba Idris nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Baba Idris suffered injuries including deafness, loss of

speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

237. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

238. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

239. Sani Bashir was a three (3) year-old male whose guardian was Mallam Mohamed Bashir. Sani Bashir was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Sani Bashir to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Sani Bashir and his family informed that there were safe and effective alternative treatments at IDH.

240. Neither Sani Bashir nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Sani Bashir suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

241. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

242. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

243. Maryam Ubah was a sixteen (16) year-old female whose guardian was Alhaji Ubah. Maryam Ubah was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was and her

family informed that there were safe and effective alternative treatments at IDH.

244. Neither Maryam Ubah nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Maryam Ubah suffered injuries including psychological and emotional trauma, amputation of limbs, apprehension of death and death itself.

245. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

246. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

247. Aminu Idris was a sixteen (16) year-old male whose guardian was Mallam Idris. Aminu Idris was brought by his parents to the IDH Hospital, to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was and his family informed that

there were safe and effective alternative treatments at IDH.

248. Neither Aminu Idris nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Aminu Idris suffered injuries including psychological and emotional trauma, amputation of limbs, apprehension of death and death itself.

249. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

250. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

251. Hassan Ibrahim was a three (3) year-old female whose guardian was Mallam Hassan Ibrahim. Hassan Ibrahim was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Hassan Ibrahim to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for

participation in the experiment, nor was Hassan Ibrahim and her family informed that there were safe and effective alternative treatments at IDH.

252. Neither Hassan Ibrahim nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Hassan Ibrahim suffered injuries including severe joint pains, body pains, deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

253. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

254. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

255. Masjbatu Shuaibu was a three (3) year-old female whose guardian was Alhaji Shuaibu. Masjbatu Shuaibu was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept her from public sight when enrolled by Pfizer in the Kano Trovan Test without family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Masjbatu

Shuaibu to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Masjbatu Shuaibu and her family informed that there were safe and effective alternative treatments at IDH.

256. Neither Masjbatu Shuaibu nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Masjbatu Shuaibu suffered injuries including general body pain, psychological and emotional trauma, amputation of limbs, apprehension of death and death itself.

257. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

258. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

259. Shamisiya Sale was an eight (8) year-old female whose guardian was Mallam Abdullahi Sale. Shamisiya Sale was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano

Trovan Test without family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Shamisiya Sale to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Shamisiya Sale and her family informed that there were safe and effective alternative treatments at IDH.

260. Neither Shamisiya Sale nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Shamisiya Sale suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

261. As a result of the injuries sustained by Shamisiya Sale the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

262. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

263. Yahaya Ibrahim was a nine (9) year-old male whose guardian was Mallam Ibrahim Amyarawa was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its

Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Yahaya Ibrahim to accurately diagnose bacterial meningitis, nor did they provide parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Yahaya Ibrahim and his family informed that there were safe and effective alternative treatments at IDH.

264. Neither Yahaya Ibrahim nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Yahaya Ibrahim suffered injuries including deafness, loss of speech, psychological and emotional trauma, and branding with the acronym "dankurma", which is a derogatory expression for "deaf and dumb" in the Nigerian northern communities, apprehension of death and death itself.

265. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

266. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

267. Nasitu Abubakar was a five (5) year-old male whose guardian was Mallam Abdu Abubakar

was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was and his family informed that there were safe and effective alternative treatments at IDH.

268. Neither Nasitu Abubakar nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Nasitu Abubakar suffered injuries including amputation of limbs, psychological and emotional trauma, apprehension of death and death itself.

269. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

270. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

271. Hodiza Yusuf was a five (5) year-old female whose guardian was Mallam Yusuf. Hodiza

Yusuf was brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Hodiza Yusuf to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was and her family informed that there were safe and effective alternative treatments at IDH.

272. Neither Hodiza Yusuf nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and she suffered injuries including amputation of limbs, psychological and emotional trauma, apprehension of death and death itself.

273. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

274. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

275. Abubakar Sheu was a nine (9) year-old whose guardian was Mallam Dauda Yusuf was

brought by her parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon she was taken away and separated from her parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without her family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Abubakar Sheu to accurately diagnose bacterial meningitis, nor did they provide her parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for her participation in the experiment, nor was Abubakar Sheu and her family informed that there were safe and effective alternative treatments at IDH.

276. Neither Abubakar Sheu nor her parents were informed that Pfizer was offering experimental treatment or consent to such treatment and Abubakar Sheu suffered injuries including severe chest pain, amputation of limbs, psychological and emotional trauma, apprehension of death and death itself.

277. As a result of her injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

278. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which she engaged prior to the date of the injury and her ability to get around and enjoy life's offerings has been vitiated.

279. Mustapha Yakubu was a three (3) year-old male whose guardian was Maliam Mohammed Sheu. Mustapha Yakubu was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Mustapha Yakubu to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Mustapha Yakubu and his family informed that there were safe and effective alternative treatments at IDH.

280. Neither . Mustapha Yakubu nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and suffered injuries including severe chest pain, amputation of limbs, psychological and emotional trauma, apprehension of death and death itself.

281. As a result of his injuries the minor plaintiff's earning capacity as well as his future earning capacity is permanently impaired.

282. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

283. Ashiru Ibrahim was a two (2) year-old male whose guardian was Mallani Yakubu Ibrahim. Ashiru Ibrahim was brought by his parents to the IDH Hospital to seek treatment and while awaiting that treatment was chosen by the defendant Pfizer for its Kano Trovan Test, specifically selected among the other people who were seeking treatment. Thereupon he was taken away and separated from his parents and kept from public sight when enrolled by Pfizer in the Kano Trovan Test without his family's full consent or knowledge. Apparently Pfizer did not conduct sufficient testing on Ashiru Ibrahim to accurately diagnose bacterial meningitis, nor did they provide his parents with basic information through a written consent form or an oral assertion about the Kano Trovan Test or seek their informed consent for his participation in the experiment, nor was Ashiru Ibrahim and his family informed that there were safe and effective alternative treatments at IDH.

284. Neither Ashiru Ibrahim nor his parents were informed that Pfizer was offering experimental treatment or consent to such treatment and he suffered injuries including severe chest pain, amputation of limbs, psychological and emotional trauma, apprehension of death and death itself.

285. As a result of his injuries the minor plaintiff's earning capacity as well as future earning capacity is permanently impaired.

286. As a further result of the injuries, the minor plaintiff has been restricted from pursuing the activities in which he engaged prior to the date of the injury and his ability to get around and enjoy life's offerings has been vitiated.

287. Each of the plaintiffs who were subject to. the Kano Trovan Test and received Trovan from the defendant Pfizer, Inc. and/or its agents, employees, representatives or servants may be suffering from undiagnosed liver damage and/or joint damage which has been correlated to Trovan, and Pfizer did not perform an initial liver screening prior to administering Trovan to the plaintiffs, nor did it do liver monitoring tests to insure that the plaintiffs' livers were not damaged nor did Pfizer conduct any MRI's or orthopedic examinations to test for joint damage to said plaintiffs and ignored or misdiagnosed or misconstrued or mischaracterized the evidence of joint pain and damage that was present in the Kano Trovan test data relating to the plaintiffs.

288. The plaintiffs also received improperly administered or administered inadequate doses of Ceftriaxone and suffered the consequences of an illness that would have been abated or diminished.

289. On December 30, 1996 Pfizer, Inc. applied with the FDA to seek approval to market Trovan in the United States including the treatment of infectious diseases in children, including but not limited to bacterial meningitis.

290. On or about June of 1997 FDA inspectors at Pfizer's Groton, Connecticut facility uncovered almost fifty inconsistencies in the Pfizer data from the Kano Trovan drug test experiment in Kano, Nigeria. Pfizer thereafter withdrew its application to use the drug against epidemic meningitis after the FDA and/or its agents, servants, employees or other federal regulators indicated that Pfizer's application more likely than not would be

denied, including the failure to conduct adequate follow-up examinations. Trovan, was given FDA approval only for a number of adult illnesses on or about December 17, 1997.

291. Soon after Trovan was approved Pfizer and the FDA began to receive reports of Trovan patients suffering from liver damage, and in June, 1999 the European Union's Committee for Proprietary Medicinal Products suspended the sales of Trovan for one year and later extended the ban in futuro.

292. Pfizer continued to seek to market Trovan to children and in 1998 and 1999 was conducting tests with Trovan against bacterial meningitis in United States children utilizing information that they received concerning the drug's toxicity in pediatric patients relating to the Kano Trovan Test.

293. The European Union Committee for Proprietary Medicine Products has refused to allow Trovan to be marketed to children in part based on the findings of the Kano Trovan deaths.

294. In January, 1999 the FDA recommended Trovan be prescribed only to patients in nursing homes or hospital settings when they were suffering life threatening conditions.

295. On June 9, 1999 the FDA issued a public health advisory on liver toxicity associated with Trovan following reports of acute liver failure associated with the drug. The FDA informed physicians that Trovan should be used only in patients who meet specific criteria, and Pfizer agreed

to limit distribution of Trovan to hospitals and long-term care nursing facilities.

296. The FDA issued an advisory indicating that Trovan-associated liver failure appears to be unpredictable and occur with minimal exposure.

## V. FRAUDULENT CONCEALMENT AND/OR CONTINUING COURSES OF CONDUCT/TOLLING OF STATUTE OF LIMITATIONS

297. The defendant concealed from the plaintiffs the material facts concerning the 1996 Kano Trovan Test, and the plaintiffs were thus unaware that the children who were involved in that test and particularly the plaintiffs were subject of an experimental drug test and that their consent was required. They did not and could not have discovered this that they had participated in a biomedical research experiment which:

(a) did not properly inform them of the risks;

(b) failed to provide adequate follow-up care;

(c) failed to conduct proper initial screening tests;

(d) failed to screen patients for kidney failure;

(e) failed to screen patients for anemia;

(f) utilizing experienced staff;

(g) failed to provide adequate patient care;

(h) failed to indicate that the oral formulation had never been given to children other than one child before;

(i) failed to take into consideration that the children were malnourished;

(i) failed to give a proper dosage of Ceftriaxone to the control group;

(j) failed to disclose that all members could inform the plaintiffs that they were conducting an experiment and that participation was optional or that alternative treatment was available on site. The plaintiffs did not and could not know this.

298. The plaintiffs did not and could not realize or discover the improprieties referred to within this complaint with regard to the Kano Drug Test until the federal government of Nigeria constituted a panel of inquiry to look into the activities of Pfizer concerning the 1996 Kano Drug Test which panel began its inquiry in May, 2001 and determined findings in August, 2001 but for which said findings still have not been made available to the public. Also there was an article written which appeared on December 17, 2000 in the Washington Post which began to detail the improprieties of the Pfizer Kano Drug Test. This newspaper is not readily available in the Republic of Nigeria,, nor is it read by the citizenry on the whole. Moreover, on December 17, 2000 by way of the internet Pfizer, Inc.

responding to said newspaper article effectively denied any of the allegations of the improprieties and continued to maintain that it did nothing wrong with regard to the Kano drug testing and continued to conceal from the plaintiffs the material facts concerning said drug testing leading to any improprieties thereto. Said denials and concealment were contained in a press release issued by Pfizer, Inc. from the United States on December 17, 2000 and said concealment and continuing course of conduct continues to the present.

299. The defendant had a special relationship with the plaintiffs in that the defendant, its agents, servants or employees and physicians had a physicians/patients relationship with the plaintiffs and also under the International Law cited within this complaint had a special relationship and obligation and duty that continued by virtue of the Nuremberg Code, the Declaration of Helsinki and the International Covenant on Civil and Political Rights (CIOMS) Guidelines and based on the aforementioned, the defendant had:

(a) An obligation and duty to follow up on the medical condition and continuing obligation for same with regard to those plaintiffs who are still living;

(b) An obligation to provide ongoing medical care to evaluate the liver and joint function of the children who are alive and to treat any abnormalities so detected;

(c) An obligation to provide counseling to those parents of children that have died;

(d) An obligation to provide continuing care to the plaintiffs or the parents of the children with regard to their potential exposure to the bacterial meningitis of those children that had died.

## VI. CLAIMS FOR RELIEF

### FIRST CLAIM FOR RELIEF: CONNECTICUT UNFAIR TRADE PRACTICES ACT. - CONNECTICUT GENERAL STATUTES §42-110a, ET SEQ

300. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

301. The plaintiffs and defendant both qualify as a person under Connecticut General Statutes §42-110a(3), and the defendant's activities referred to in this Complaint with regard to all the improprieties referred to within this Complaint and with regard to the defendant's actions in promulgating and organizing and planning and distributing and/or advertising and/or providing the services relating to the Trovan drug trials and in producing and performing preliminary testing of Trovan and designing the Kano treatment protocol in the United States and conducting those activities in trying to circumvent FDA regulations with the ultimate goal of marketing Trovan domestically, and the defendant Pfizer, Inc. being involved in the back-

dating of the Ethics Committee letter and all the other improprieties relating to the Trovan drug test referred to within this Complaint and in:

(a) Failing to disallow Pfizer employees from participating in the medical study themselves;

(b) Failing to provide any follow-up care after the Trovan drug trials were terminated by the defendant to determine what impact the Kano Trovan test had on its participants and if there were any untoward effects what could be done to ameliorate them;

(c) Deviating from its own protocol in violation of international law more fully referred to within this complaint;

(d) Failing to put the best medical interests of the plaintiffs above the defendant's interests in initially marketing and securing FDA approval for Trovan;

(e) Failing to abide by the Nuremberg Code, the ICCPR, the Declaration of Helsinki, the CIOMS Guidelines and FDA Regulations.

(f) Back-dating necessary approvals;

(g) Organizing, collating, and recording data known to be inaccurate or improper while in

Groton, Connecticut and found by the FDA on or about June, 1997, which data was still concealed from the plaintiffs.

302. All these actions referred to within this first Claim for Relief and the improprieties of the Kano Drug Test as well as the concealment thereof taken singularly or in combination were unfair, deceptive and/or immoral and deceptive practice in the conduct of trade or commerce by the defendant in violation of Connecticut General Statutes §42-110(b)(a).

303. At all times mentioned in this Complaint defendant was a Delaware corporation doing business in the State of Connecticut, particularly at its Groton, Connecticut headquarters where it conducted and conducts global research and development of pharmaceutical products and has over two million square feet of laboratory space and employs in a range of four thousand research scientists, technicians, clinicians and related professionals, and the defendant was a manufacturer and/or wholesaler and and/or distributor and/or retailer selling and/or re-selling and/or providing for use or consumption pharmaceuticals and in particular Trovan.

304. Pursuant to Connecticut General Statutes § 42-110(g)(c), the plaintiffs are mailing a copy of this Complaint to the State of Connecticut Attorney General.

305. The unfairness and deceptive immoral and oppressive acts or practices or unfair methods of competition caused the plaintiffs damages as

referred to in this complaint including personal injuries and more specifically including for the pertinent plaintiffs deafness, blindness, paralysis, physical and mental suffering and for some of the plaintiffs, death, and the parents' mental suffering and cost of care and loss of services and the defendant's continued course of conduct as aforesaid violated and breached its duty to the patients with regard to their follow-up care for those who survived and/or failing to continue to monitor those surviving plaintiffs and trying to ameliorate their present conditions caused by the administering of the Trovan or low- dosing of the control drug and with ongoing testing to evaluate their liver function and/or damage and/or joint function and/or body functioning that were impaired by the Trovan drug testing and by failing to perform proper follow up with these surviving members of the decedent minor plaintiffs to review and test and consider and limit the exposure of the surviving parents and/or guardians of the deceased minor plaintiffs to the original bacterial meningitis and the financial loss suffered by the plaintiffs.

**SECOND CLAIM FOR RELIEF : CONNECTICUT PRODUCTS LIABILITY ACT - CONNECTICUT GENERAL STATUTES §52-572(m), ET SEQ**

306. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

307. At all times mentioned in this complaint the defendant was a Delaware corporation doing business in the State of Connecticut, particularly at its Groton, Connecticut headquarters where it

conducted and conducts global research and development of pharmaceutical products and has over two million square feet of laboratory space and employs in a range of four thousand research scientists, technicians, clinicians and related professionals, and the defendant was a manufacturer and/or wholesaler and and/or distributor and/or retailer selling and/or re-selling and/or providing for use or consumption pharmaceuticals and in particular Trovan.

308. The defendant at the time of this incident described in this complaint was engaged in the business of manufacturing and/or designing and/or formulating and/or preparing and/or assembling and/or testing and/or marketing and/or packaging and/or labeling the drug trovafloxacin mesylate which Pfizer gave the brand name Trovan.

309. Trovan was manufactured and designed, formulated and prepared, tested and marketed and package by the defendant with the expectation that Trovan would reach the plaintiffs without substantial change in its condition.

310. Trovan was not altered or modified in any way by the plaintiffs or any third-party from the condition in which it was manufactured, formulated and/or prepared by the defendant.

311. The defendant Pfizer, Inc. had reasonable expectation that Trovan would be used and was in fact so used by the plaintiffs' minor children by virtue of the preparation, execution, distribution and eventual use by the plaintiffs.

312. The defendant Pfizer, Inc.is liable and legally responsible to the plaintiffs for the injuries

caused by the use of Trovan and by virtue of Connecticut General Statutes §52-572(m) et seq. as amended (Products Liability law) in one or more of the following respects:

(a) In that the use of Trovan under the circumstances described within this Complaint and was an unreasonably dangerous use and could not be used without reasonable risk of injury to the plaintiffs and the Trovan was expected to and did reach the plaintiffs without substantial change from its original manufacture and formulation and preparation;

(b) In that the defendant failed to warn or instruct the plaintiffs;

(c) in that if warnings or instructions were given with regard to the use of Trovan they were inadequate and failed to provide sufficient notice to the plaintiffs of the dangerous propensities of Trovan;

(d) In that the defendant misrepresented to the plaintiffs and the general public that Trovan was safe for use by the public and children;

(e) in that the defendant failed to disclose to the plaintiff and the

general public the dangerous propensities of Trovan;

(f) In that the defendant was negligent in that it:

1. failed to properly and adequately test Trovan prior to its manufacture and/or formulation and/or soliciting and/or marketing and/or advertising;

2. knew or should have known of the dangerous characteristics of Trovan yet continued its manufacture and/or formulation and/or marketing and/or soliciting and/or advertising and/or testing;

(g) In that it warranted and represented to the plaintiffs and persons similarly situated that Trovan was safe even though the defendant knew this was not true or should have known that this was not true;

(h) In that the defendant breached its duty of care to the plaintiffs in that it knew or should have known that Trovan was dangerous and inappropriate for the use intended;

(i) In that the defendant breached the express warranties that

Trovan was safe and effective for its intended use;

(j) In that the defendant breached the implied warranty of merchantability and fitness of the product for the purposes for which it was intended in that Trovan was not appropriate for its intended use.

313. As a result of the defendant's actions, the children enrolled in the Kano Trovan Test and their parents suffered damages, including the right to withhold consent, the children's deafness, blindness, paralysis, mental and physical suffering and death, and the parents' mental suffering, costs of care and loss of services.

314. As a result of-their injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

315. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date of the injury and their ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities and life's offerings have been vitiated.

**THIRD CLAIM FOR RELIEF: RECKLESSNESS PURSUANT TO THE CONNECTICUT PRODUCTS LIABILITY ACT:**

316. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

317. The defendant Pfizer, Inc.is liable and legally responsible to the plaintiffs by virtue of Connecticut General Statutes §52-240b in that the injuries and losses caused by the use of Trovan resulted from the defendant Pfizer, Inc.'s reckless disregard for the safety of product users or consumers and others in the following respects:

(a) in that the defendant manufactured and/or formulated and/or distributed and/or advertised and/or marketed and/or tested the Trovan and it knew or should have known that the Trovan was dangerous and inappropriate for use;

(b) in that the defendant inaccurately warned of the dangers involving the use of Trovan to the plaintiffs notwithstanding that it knew or should have known that Trovan was dangerous or inappropriate for use.

318. As a result of the defendant's actions, the children enrolled in the Kano Trovan Test and their parents suffered damages, including the right to withhold consent, the children's deafness, blindness, paralysis, mental and physical suffering and death, and the parents' mental suffering, costs of care and loss of services.

319. As a result of their injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

320. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date of the injury and their ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities and life's offerings have been vitiated.

**FOURTH CLAIM FOR RELIEF: (UNDER INTERNATIONAL LAW: FAILURE TO OBTAIN INFORMED CONSENT)**

321. Plaintiffs incorporate, by reference all the other paragraphs of this Complaint as if fully set forth herein.

322. International Law, particularly the Nuremberg Code, the Declaration of Helsinki, Article 7 of the ICCPR and the CIOMS Guidelines requires that medical researchers receive informed consent.

323. The defendant did not secure plaintiffs' informed consent or any consent prior to enrolling the plaintiff children in its test of Trovan.

324. As a result of the defendant Pfizer, Inc.'s actions, the children enrolled in the Kano Trovan Test and their parents suffered damages, including the right to withhold consent, the children's deafness, blindness, paralysis, psychological and emotional trauma, mental and physical suffering and death, and the parents' mental suffering, cost of care and loss of services.

325. As a result of their injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

326. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date of the injury and their ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities, and life's offerings have been vitiated.

**FIFTH CLAIM FOR RELIEF:**
**(INTERNATIONAL LAW: BREACH OF DUTY TO PROVIDE THE BEST PROVEN DIAGNOSTIC AND THERAPEUTIC METHODS)**

327. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

328. International Law as evidenced by, inter alia, the Nuremberg Code, the Declaration of Helsinki and the CIOMS Guidelines requires that medical researchers provide the best proven diagnostic and therapeutic methods.

329. The defendant breached this duty by failing to properly diagnose patients as suffering from bacterial meningitis though the use of CFS analyses, which is the internationally accepted method for diagnosing meningitis.

330. The defendant also breached this duty by abandoning efforts to test patients' blood as planned.

331. The defendant also breached this duty by giving Trovan to critically-ill Nigerian children despite the availability of alternative, non-toxic, proven drugs.

332. The defendant also breached this duty by failing to alter the therapy provided to children who did not respond to treatment provided in the Trovan experiment and by failing to use alternative proven treatment for such children.

333. The defendant also breached this duty by intentionally low dosing (administering one-third of the recommended dosage) Ceftriaxone to patients in the control group.

334. The defendant also breached this duty by failing to provide adequate follow-up care to patients enrolled in its experiment and by improperly injecting the control drug.

335. As a result of the defendant Pfizer, Inc.'s actions, the children enrolled in the Kano Trovan Test and their parents suffered damages, including the right to withhold consent, the children's deafness, blindness, paralysis, mental and physical suffering and death, and the parents' mental suffering, cost of care and loss of services.

336. As a result of their, injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

337. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date of the, injury and their ability to get around and enjoy life's offerings have been impaired and will be

so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities and life's offerings have vitiated.

**SIXTH CLAIM FOR RELIEF - (UNDER INTERNATIONAL LAW – BREACH OF DUTY TO TREAT WITH DIGNITY)**

338. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

339. International Law as evidenced by, inter alia, the Nuremberg Code and Helsinki Declaration recognizes the right of every human subject to be treated with dignity in the conduct of a clinical trial.

340. The defendant's conduct during the Kano Trovan Test as set forth herein, breached plaintiffs' rights to be treated with dignity as set forth in the Nuremberg Code and Declaration of Helsinki.

341. The defendant Pfizer, Inc.'s actions caused the children enrolled in the Kano Trovan Test and their parents to suffer damages, including the children's deafness, blindness, paralysis, psychological and emotional trauma, mental and physical suffering and death, and the parents' mental suffering, cost of care and loss of services.

342. As a result of their injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

343. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date

of the injury and their ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities and life's offerings have been vitiated.

**SEVENTH CLAIM FOR RELIEF: (UNDER INTERNATIONAL LAW: BREACH OF RIGHT TO BE FREE FROM CRUEL, INHUMAN AND DEGRADING TREATMENT)**

344. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

345. International Law as evidenced by, inter alia, Article 7 of the ICCPR considers medical testing without informed consent as torture or cruel or inhuman punishment which is forbidden under International Law as evidenced by Article 5 of the Universal Declaration of Human Rights.

346. The defendant's conduct during the Kano Trovan Test as set forth herein, breached plaintiffs' rights to be treated with dignity as set forth in the Nuremberg Code and Declaration of Helsinki.

347. As described herein, the defendant Pfizer, Inc. conducted the Kano Trovan Test without seeking plaintiffs' informed consent, or in fact any consent from the children enrolled and/or their parents and/or their guardians. The plaintiffs were not. informed the "treatment" provided to the children enrolled in the Kano Trovan Test was experimental in nature.

348. The defendant's conduct constituted torture or cruel or inhuman punishment in violation of the law of nations.

349. The defendant's conduct was intentional and/or reckless, and was so outrageous in character and extreme in degree as to go beyond all possible bounds of decency, and to be regarded as atrocious and intolerable in a civilized community.

350. The defendant's conduct caused the children enrolled in the Kano Trovan Test and their parents and/or guardians to suffer damages, including the children's deafness, blindness, paralysis, physical, psychological and emotional trauma, and mental suffering and death, and the parents' mental suffering, cost of care and loss of services.

351. As a result of their injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

352. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date of the injury and their ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities and life's offerings have been vitiated.

**EIGHTH CLAIM FOR RELIEF: FRAUDULENT CONCEALMENT PURSUANT TO CONNECTICUT GENERAL STATUTES S52-595**

353. Plaintiffs incorporate by reference all the other paragraphs of this Complaint as if fully set forth herein.

354. The defendant was aware of the facts cited within this Complaint concerning the improprieties of the Trovan Drug Testing and intentionally concealed same from the plaintiffs and continued such concealment and continues such concealment to the present date.

355. The defendant was aware of facts necessary to know that the plaintiffs would have a cause of action against them for pursuant to all the improprieties alleged within this Complaint and the defendant intentionally concealed said facts from the plaintiffs to delay any filing of a complaint or cause of action in a court or regulatory body of competent jurisdiction, and the defendant continued to deny the improprieties of the Trovan Drug Testing in their response on December 17, 2000 to a *Washington Post* newspaper article appeared on said date and as well as responses to inquiries by the Nigerian government that began in May, 2001.

356. As a result of .the defendant Pfizer, Inc.'s actions, the children enrolled in the Kano Trovan Test and their parents suffered damages, including the right to withhold consent, the children's deafness, blindness, paralysis, mental and physical suffering and death, and the parents' mental suffering, cost of care and loss of services.

357. As a result of their injuries the minor plaintiffs' earning capacity as well as future earning capacity is permanently impaired.

358. As a further result of the injuries, the minor plaintiffs have been restricted from pursuing the activities in which they engaged prior to the date of the injury and their ability to get around and enjoy life's offerings have been impaired and will be so affected for the remainder of their lives. For the decedent plaintiffs, they can no longer enjoy said activities and life's offerings have been vitiated.

## X. INJUNCTIVE EQUITABLE AND MONETARY RELIEF.

359. The defendant had and has a continuing duty to warn the living plaintiffs and other subjects of the Kano Trovan Test of all potential risks and dangers of which it becomes or should become aware and to warn those guardians representing children who died as to what effect it would have on them, their surviving families and guardians.

360. The defendant should be required to ameliorate the present conditions of the surviving plaintiffs that are caused by the administration of Trovan or the low-dosing of the control drug Ceftriaxone and requiring the defendant to treat the surviving plaintiffs with any abnormalities and to provide counseling to those parents of the children who have died due to the Kano Trovan Drug Test as well as advising them with regard to their exposure to the bacterial meningitis that was suffered by their deceased children and to provide the surviving plaintiffs it experimented upon with ongoing testing to evaluate their liver function and/or damage and their joint function and/or damage.

361. Defendant should be enjoined from conducting further testing, pre-market or otherwise,

on any person, without first obtaining informed consent consistent with FDA regulations.

362. Defendants should be required to pay plaintiffs compensatory damages.

## XI. ENTITLEMENT TO PUNITIVE DAMAGES

363. Plaintiffs are entitled to punitive damages because the defendant's conduct was wanton and outrageous an because the defendant acted with a motive to deceive plaintiffs and their young, sick children regarding the nature, safety and efficacy of the treatment being provided.

364. Plaintiffs are also entitled to punitive damages because the defendant's reckless indifference to the rights of the plaintiffs to make an informed consent prior to their children and charges being enrolled in a medical experiment.

365. Plaintiffs are claiming entitlement to punitive damages in that the test violated international law; federal law; and medical ethical standards, but the defendant took no corrective action.

366. Plaintiffs are further claiming entitlement to punitive damages because Pfizer chose as its victims sick, impoverished, Muslim Nigerian children who were particularly vulnerable and thus deserving of special care and protection.

367. The plaintiffs are also claiming entitlement to punitive damages under Connecticut General Statutes §42-110g(a) and §42-110g(d).

368. Plaintiffs are further claiming entitlement to punitive damages pursuant to Connecticut General Statutes §52-240b.

369. Pfizer is one of if not the world's largest, pharmaceutical company, with revenues in excess of sixteen billion dollars as of 1999, will not be deterred in the future from the type of conduct complained of herein unless very substantial punitive damages are imposed.

**WHEREFORE, THE PLAINTIFFS PRAY FOR RELIEF AS FOLLOWS:**

a. Award plaintiffs compensation in the amount of FIVE MILLION DOLLARS ($5,000,000.00) PER PLAINTIFF;

b. An Order requiring the defendant to pay TWENTY-FIVE MILLION DOLLARS ($25,000,000.00) PER PLAINTIFF IN PUNITIVE DAMAGES;

c. An Order requiring the defendant to provide ongoing medical care to evaluate the liver and joint function of the children and any other abnormality caused by the Kano Drug Testing experiment and requiring the defendant to treat any abnormalities so detected and to provide counseling to those parents of the children that have died due to the Kano Trovan Test;

d. Attorneys' fees, expenses and costs of this action; and

e. Such further relief as this Court deems necessary, just and proper.

## DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury in this action pursuant to Federal Rule of Civil Procedure 38(b) and Local Rule 7(a)2.

Dated this 27th day of November, 2002.

THE PLAINTIFFS

By s/ Richard Altschuler

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